Front Side

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SYROMAK 10 ODT
Dolutegravir sodium 10.52 mg equivalent to dolutegravir 10 mg
Contains sugar (29.08 mg mannitol) & sweetener (1.20 mg sucralose)

Read all of this leaflet carefully before you start taking SYROMAK 10 ODT
Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
SYROMAK 10 ODT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SYROMAK 10 ODT is and what it is used for
2. What you need to know before you take SYROMAK 10 ODT
3. How to take SYROMAK 10 ODT
4. Possible side effects
5. How to store SYROMAK 10 ODT
6. Contents of the pack and other information

1. What SYROMAK 10 ODT is and what it is used for

SYROMAK 10 ODT contains dolutegravir sodium.

SYROMAK 10 ODT is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called integrase inhibitors (INIs).

SYROMAK 10 ODT is used to treat HIV (human immunodeficiency virus) infection in adults, adolescents and children in combination with other anti-retroviral medicines.

2. What you need to know before you take SYROMAK 10 ODT

Do not use SYROMAK 10 ODT:
- if you are hypersensitive (allergic) to dolutegravir or any of the other ingredients of SYROMAK 10 ODT
- if you are taking another medicine called dofetilide or phlecainide (to treat heart conditions)
- if you have severe liver disease
- if you are in the first 1 trimester of your pregnancy and if you are breastfeeding
- if you (or your child) are taking another medicine called lamotrigine (also known as carbamazepine; used in epilepsy & schizophrenia).

Warnings and precautions
Take special care with SYROMAK 10 ODT
- if you develop a rash. Some people taking SYROMAK 10 ODT have had allergic rash, fever,
- if you get any symptoms of infection while you are taking SYROMAK 10 ODT:
  People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections (such as tuberculosis) flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.
- if you experience joint pain, stiffness and bone problems
- Keep in touch with your doctor, and do not stop taking SYROMAK 10 ODT without your doctor's advice.
  HIV can still be transmitted despite taking SYROMAK 10 ODT. SYROMAK 10 ODT does not cure HIV infection; it reduces the amount of virus in your body.
- While you are taking SYROMAK 10 ODT, you will need regular blood tests.
  For as long as you are taking SYROMAK 10 ODT, your doctor will arrange regular blood tests to check for side effects. There is more information about these side effects in this leaflet. See section 4.
- You need to know about important signs and symptoms to look out for while you (or your child) are taking SYROMAK 10 ODT.
  Read the information in Section 4 of this leaflet.
- Protect other people.
  HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). SYROMAK 10 ODT will not stop you passing HIV infection on to other people. Take protective steps to prevent infection with HIV:
  - Use a condom when you have oral or penetrative sex.
  - Do not risk blood transfer - for example, don't share needles.

Use in children and adolescents
Children
Do not give this medicine to children under 4 weeks of age, weighing less than 3 kg or with HIV infection that is resistant to other medicines similar to SYROMAK 10 ODT. The use of SYROMAK 10 ODT dispersible tablets in children under 4 weeks or weighing less than 3 kg has not yet been studied.
Children must keep planned doctor's appointments (see 'Children and adolescents' in Section 4 for more information).

Other medicines and SYROMAK 10 ODT
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
- Dofetilide or phlecainide, to treat heart conditions
Some medicines can affect how SYROMAK 10 ODT works or make it more likely that you will have side effects. These include:
- metformin, to treat diabetes
- medicines called antacids, to treat indigestion and heartburn. Do not take an antacid during the 6 hours before you take SYROMAK 10 ODT, or for at least 2 hours after you take
- calcium and iron supplements. Do not take a calcium or iron supplement during the 6 hours before you take SYROMAK 10 ODT, or for at least 2 hours after you take it
- efavirenz, etravirine, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection
- rifampicin, to treat tuberculosis and other bacterial infections
- phenytoin and phenobarbitone, to treat epilepsy
- carbamazepine, to treat epilepsy and bipolar disorder
- St. John's wort, (Hypericum perforatum), a herbal remedy, to treat depression.

Tell your doctor or pharmacist if you are taking any of these. Your doctor may decide to adjust your dose or that you need extra check-ups.

SYROMAK 10 ODT with food and drink and alcohol
SYROMAK 10 ODT can be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
You should not use SYROMAK 10 ODT during pregnancy.
Safe use during pregnancy and breastfeeding has not been established.
If you are of the age of taking pregnant, you should have a negative pregnancy test before you start taking SYROMAK 10 ODT.
While you are taking SYROMAK 10 ODT you must use a reliable method of contraception, to prevent pregnancy.
Women who are HIV-positive should not breastfeed their babies because HIV infection can be passed on to the baby in breast milk.
Talk to your doctor immediately if you are breastfeeding or thinking about breastfeeding.

Driving and using machines
SYROMAK 10 ODT can make you dizzy and have other side effects that make you less alert. Do not drive or use machines unless you are sure you are not affected.
It is not always possible to predict to what extent **SYROMAK 10 ODT** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **SYROMAK 10 ODT** affects you.

Important information about some of the ingredients of SYROMAK 10 ODT
This product contains less than 1 mmol sodium (23 mg) per tablet that is to say is essentially 'sodium free'.

3. How to take SYROMAK 10 ODT

Do not have medicines prescribed for you with any other person

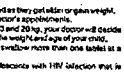
Always take **SYROMAK 10 ODT** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
The usual dose is:
Adults
- The usual dose of **SYROMAK 10 ODT** is 30 mg (three 10 mg dispersible tablets), once a day; or
- For HIV infection that is resistant to other medicines similar to **SYROMAK 10 ODT**, the usual dose of **SYROMAK 10 ODT** is 50 mg (five 10 mg dispersible tablets), taken a day.
- Your doctor will decide on the correct dose of **SYROMAK 10 ODT** for you.

Children and adolescents:
Your doctor will decide on the correct dose of **SYROMAK 10 ODT** for your child, depending on the weight of the child.
- Children's dose of **SYROMAK 10 ODT** needs to be adjusted as they get older or gain weight.
  - It is important therefore that children keep planned doctor's appointments.
- For children aged at least 4 weeks and weighing between 3 and 20 kg, your doctor will decide on the correct dose of **SYROMAK 10 ODT**, depending on the weight and age of your child.
- If swallowing tablets whole with water, children must not swallow more than one tablet at a time because the risk of choking.

SYROMAK 10 ODT should not be used in children and adolescents with HIV infection that is resistant to other medicines similar to SYROMAK 10 ODT.
Method of administration
- The dispersible tablets may be dispersed in drinking water or swallowed whole with drinking water.
- When dispersed, the amount of water will depend on the number of tablets prescribed. The tablet(s) should be fully dispersed before swallowing.
- Do not chew or crush the tablets.
- **SYROMAK 10 ODT** can be taken with or without food. When **SYROMAK 10 ODT** is taken twice-a-day, your doctor may advise you to take with food.
- You must give the dose of medicine within 30 minutes of preparing the dose. If it has been more than 30 minutes wash the dose away and prepare a new dose of medicine.

Instructions for Use:
If your child is able and prefers to swallow the tablets, then you may use the following steps
Pour water:

Water Volume Guide					
Number of tablets	Half	1	one and a half	2	Two and a half
Volume of water	5 ml.		10 ml.		



- Pour clean drinking water into the cup.
  The water volume guide above shows you the amount of water needed for the prescribed dose.

Use drinking water only.
Do not use any other drink or food to prepare the dose.
How to prepare the medicine:



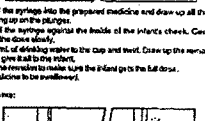
- Add the prescribed number of tablet(s) to the water.
- Swirl the cup gently for 1 to 2 minutes to disperse the tablet(s). The medicine will become cloudy. Take care not to spill any of the medicine.
- Check that the medicine is ready. If there are any lumps of tablet swirl the cup until they are gone.

If you spill any medicine, clean up the spill.
Throw away the rest of the prepared medicine and make a new dose.
You must give the dose of medicine within 30 minutes of preparing the dose. If it has been more than 30 minutes wash the dose away and prepare a new dose of medicine.
Giving the medicine:



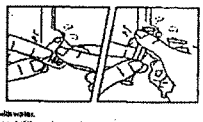
- Make sure that the child is upright. Give all the prepared medicine to the child.
- Add another 5 ml of drinking water to the cup, swirl and give it all to the child.
- Repeat if any medicine remains to make sure the child gets the full dose.

Give the medicine to the infant.



- Place the tip of the syringe into the prepared medicine and draw up all the medicine into the syringe by pulling up on the plunger.
- Place the tip of the syringe against the inside of the infant's cheek. Gently push down the plunger to give the dose slowly.
- Add another 5 mL of drinking water to the cup and swirl. Draw up the remaining medicine into the syringe and give it all to the infant.

Repeat if any medicine remains to make sure the infant gets the full dose.
Allow time for the medicine to be swallowed.
Cleaning:
Clean the dosing items:



- Wash the cap with water.
- Pull the plunger out of the syringe and wash the syringe parts separately in water. Allow parts to dry completely before reassembling and storing.

All used parts will need to be clean before preparing the next dose.
Antacid medicines
Antacids, to treat indigestion and heartburn, can also **SYROMAK 10 ODT** being absorbed into your body and make it less effective.
Do not take an antacid during the 6 hours before you take **SYROMAK 10 ODT**, or for at least 2 hours after you take it.
Other acid-lowering medicines like ranitidine and omeprazole can be taken at the same time as **SYROMAK 10 ODT.**
- Talk to your doctor for further advice on taking acid-lowering medicines with **SYROMAK 10 ODT.**

Calcium supplements, iron supplements or multivitamins
Calcium supplements, iron supplements or multivitamins can stop **SYROMAK 10 ODT** being absorbed into your body and make it less effective.
Do not take a calcium supplement, iron supplement or multivitamin during the 6 hours before you take **SYROMAK 10 ODT**, or for at least 2 hours after you take it.
- Talk to your doctor for further advice on taking calcium supplements, iron supplements or multivitamins with **SYROMAK 10 ODT.**

If you have the impression that the effect of SYROMAK 10 ODT is too strong or too weak, talk to your doctor or pharmacist.

If you take more SYROMAK 10 ODT than you should
In the event of over dosage, consult your doctor or pharmacist, if neither is available, contact the nearest hospital or poison control centre.
Medical attention may be necessary, if you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take SYROMAK 10 ODT
If you miss a dose, **take it** as soon as you remember, but if it is within 4 hours of your next dose, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.
Do not take a double dose to make up for a missed dose.

If you stop taking SYROMAK 10 ODT
Take SYROMAK 10 ODT for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

SYROMAK 10 ODT can have side effects.
Not all side effects reported for **SYROMAK 10 ODT** are included in this leaflet. Should your general health worsen or if you experience any undesired effects while taking **SYROMAK 10 ODT**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking SYROMAK 10 ODT and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SYROMAK 10 ODT. You may need urgent medical attention or hospitalisation.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- headache, dizziness,
- inability to sleep, abnormal dreams, depression (feeling sad), feeling anxious
- Nausea, diarrhoea, vomiting, wind (flatulence), upper abdominal pain
- abnormal liver function tests (confirmed through blood tests)
- rash, itching
- feeling tired
- increase in creatine phosphokinase - enzymes produced in the muscles (confirmed through lab tests)

Less frequent side effects:
- dry cough
- muscle cramps
- tiredness or weak,
- dizziness,
- loss of appetite
- allergic reactions, immune reconstitution inflammatory syndrome - an inflammatory condition which may develop as the immune system becomes stronger
- suicide thoughts (mainly in patients who have had depression or mental health problems before)
- pain and discomfort in the abdomen
- inflammation of the liver, liver problems, increased bilirubin – a substance produced by the liver (confirmed through tests)
- muscle and joint pain

Frequency unknown
- Weight gain

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the 'Med Adverse Drug Reaction Reporting Form', found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index8. By reporting side effects, you can help provide more information on the safety of **SYROMAK 10 ODT.**

5. How to store SYROMAK 10 ODT

Store at or below 30 °C (room temperature).
Keep the HDPE container tightly closed.
Store in the original package in order to protect from moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilet).

6. Contents of pack and other information

What SYROMAK 10 ODT contains
The active ingredient is dolutegravir sodium.
Contains sugar (29.08 mg mannitol) & sweetener (1.20 mg sucralose)
This medicine contains less than 1 mmol sodium (23 mg) per tablet that is to say is essentially 'sodium free'.
Other ingredients are:
Tablet core contains:
Calcium sulphate dihydrate, crospovidone, mannitol, microcrystalline cellulose, povidone, silicified microcrystalline cellulose, sodium starch glycolate, sodium stearyl fumarate, strawberry cream flavor, sucralose
Coating material contains
Hypromellose, titanium dioxide, macrogol, carnauba red.

What SYROMAK 10 ODT looks like and contents of the pack
Pink, colored, capsul shaped, film coated tablets, debossed 'A' and 'I' separated by breakline on one side and debossed 'SX' on other side.
The tablet can be divided into equal halves.

Contents of the pack:
HDPE container
Tablets are packed in a round white HDPE container closed with child resistant closure or continuous thread closure with pulp and heat sealliner with or without silica gel.
Pack sizes include 28's, 30's and 90's tablets.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bernonile Estate Office Park (Extn),
1 Cresecile Drive, Bernonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised on
14 JUNE 2022

Registration number
SYROMAK 10 ODT: 56/20.2.8/01 N

Access to the corresponding *Professional* information
The corresponding professional information can be accessed at www.sahealthcareproducts.co.za/ or contact 011 682 1100

The Product has been manufactured under a license from the Medicines Patent Pool
The Products are not for administration to anyone other than Child Peoples
Any other use is not authorized

SYROMAK 10 ODT
PMDK235801

360 mm

335 mm

Front Side

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS [S4]

SYROMAK 10 ODT
Dolutegravirnatrium 10,62 mg ekwivalent aan 10 mg dolutegravir
Bevat suiker (29,84 mg mannitol) en Vanoxter (1,20 mg sukraloset.

Lees hierdie inligtingsluk aandagtiglik voordat jy SYROMAK 10 ODT begin gebruik.
- Hou hierdie inligtingsluk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra aanvullend jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- **SYROMAK 10 ODT is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.**

Wat sit hierdie inligtingsluk in
1. Wat SYROMAK 10 ODT is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy SYROMAK 10 ODT neem
3. Hoe om SYROMAK 10 ODT in te neem
4. Moontlike newe-effekte
5. Hoe om SYROMAK 10 ODT te bewaar
6. Inhoud van die pak en ander inligting

1. Wat SYROMAK 10 ODT is en waarvoor dit gebruik word

SYROMAK 10 ODT bevat dolutegravirnatrium.
SYROMAK 10 ODT is 'n tipe medisyne wat bekend staan as 'n anti-retrovirale middel. Dit behoort aan 'n groep medisyne wat integrase-inhibeerders (INI's) genoem word.

SYROMAK 10 ODT word gebruik om MIV (menslike immuniteitsgebrekvirus) infeksie in volwassenes, adolessente en kinders te behandel in kombinasie met ander anti-retrovirale middels.

2. Wat jy behoort te weet voordat jy SYROMAK 10 ODT neem

Moet nie SYROMAK 10 ODT gebruik nie:
- indien jy hipersensitief (allergies) vir dolutegravir of enige van die ander bestanddele van SYROMAK 10 ODT is
- indien jy 'n ander middel geneem, dolutegravir of pikotamied neem (om hierdie te behandel)
- indien jy ernstige lewersiekte het
- indien jy in die eerste trimester van jou swangerskap is en indien jy borsvoed
- indien jy col jou kind 'n ander medisyne geneem fampridien neem (ook bekend as dalfampridien, gebruik in volwassene sklerose).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met SYROMAK 10 ODT
- indien jy 'n allergie ontwikkel. Sommige mense wat SYROMAK 10 ODT neem, het allergiese reaksies gehad.
- indien jy enige simptome van infeksie by sowel jy SYROMAK 10 ODT neem.
  Mense met gevorderde MIV-infeksie (VIGS) het 'n verswakte immuunstelsel en is meer geneig om ernstige infeksies (opportunistiese infeksies) te ontwikkel. Wanneer hierdie mense met behandeling begin, kan hulle tekens dat sulke infeksies (soos tuberkulose) opduik, wat lei tot simptome van infeksiemasie veroorsaak. Hierdie simptome word waarskynlik veroorsaak deur die liggaam se immuunstelsel wat sterker word, sodat die liggaam hierdie infeksies begin beveg.
- indien jy osteroporose, styfheid en beenpyn het nie gewaar.
- Bly in kontak met jou dokter, en moet nie ophou om SYROMAK 10 ODT te neem sonder jou dokter se advies nie.
  Lê jy kan steeds oorgedra word oorlede die neem van SYROMAK 10 ODT. SYROMAK 10 ODT gewees die MIV-infeksie nie; die vermindert die hoeveelheid virus in jou liggaam.
- Te veel jy SYROMAK 10 ODT gebruik, sal jy geen of minder bloedsiekte moet hê nie.
  Vir seksie en veel jy SYROMAK 10 ODT neem, sal jou dokter gereelde bloedtoetse moet doen te kyk vir newe-effekte. Daar is meer inligting oor hierdie newe-effekte in hierdie inligtingsluk. Sien afdeling 4.
- Jy moet weet van bekommerde infeksie simptome voorkoor jy moet opdat te myl jy en jou kind. Indien hulle die pasiënt sal SYROMAK 10 ODT neem.
  Lees die inligting in Afdeling 4 wat hierdie inligting is.
- Beskerm ander mense.
  MIV-infeksie word verspreid deur seksuele kontak met iemand wat die infeksie het, of deur die oordrag van besmette bloed (byvoorbeeld deur inspuitings naaldie te deel). SYROMAK 10 ODT sal nie keer dat jy seksueel aan ander mense oordra nie. Om ander mense te beskerm moet besmetting met MIV:
  - Gebruik 'n kondoom wanneer jy seksueel penetrerende seks het.
  - Moet nie oordrag van bloed weg nie - moet byvoorbeeld nie naaldie deel nie.

Gebruik in kinders en adolessente
Kinders
Moet nie hierdie medisyne gee aan kinders jonger as 4 weke oud, wat minder as 3 kg weeg of met MIV-infeksie wat weerstandbreekend is teen ander medisyne aangepas aan SYROMAK 10 ODT nie. Die gebruik van SYROMAK 10 ODT 5 mg verspreibare tablette in kinders jonger as 4 weke oud of wat minder as 3 kg weeg, is nog nie bestudeer nie.
Kinders moet bepaalde dokters eberaike nakom (sien 'Kinders en adolessente' in Afdeling 4 vir meer inligting).

Ander medisyne en SYROMAK 10 ODT
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem, (Dit sluit alle komplementêre of apteekmedisyne in.)
- Dolutegravir plasmavlakke, vir die behandeling van hoesterstandig.
  Sommige medisyne kan beïnvloed hoe SYROMAK 10 ODT werk of dit meer waarskynlik maak dat jy newe-effekte sal hê. Dit sluit in:
- antibiotikum, om diarree te behandel
- medisyne wat teensuurmiddels genoem word, om sekere spysvertering en sooibrand te behandel. Moet nie 'n teensuurmiddel neem gedurende die 6 uur voordat jy SYROMAK 10 ODT neem nie, of vir ten minste 2 uur nadat jy dit geneem het
- tuberkulose se yeisenaweiings. Moet nie 'n tuberkulose se yeisenaweiding neem gedurende die 6 uur voordat jy SYROMAK 10 ODT neem nie, of vir ten minste 2 uur nadat jy dit geneem het nie
- etsertikie, sifelinies, koorsperenvirinfeksies, verkeplen of fynsuwerkinfeksies om MIV-infeksie te behandel
- rifabutien, om tuberkulose en ander bakteriële infeksies te behandel
- fenitoïen en fenobarbitoon, om epilepsie te behandel
- kalsiumtoepoen, om epilepsie en bipolêre versteuring te behandel
- St. Janskruid, (Hypericum perforatum), 'n kruismiddel om depressie te behandel.

Vertel jou dokter of apteker indien jy enige van hierdie gebruik. Jou dokter kan besluit om jou dosis aan te pas of dat jy vir ander medisyne beboefig.

SYROMAK 10 ODT saam met kos en vloeistowwe en alkohol
SYROMAK 10 ODT kan met of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om te raak te hê, vra jou dokter of apteker vir die advies voordat jy hierdie medisyne neem.
Jy moet nie SYROMAK 10 ODT tydens swangerskap gebruik nie.
Veilige gebruik tydens swangerskap en borsvoeding is nie vasgestel nie.
Indien jy ooit gevrug is of swanger te kan raak, moet jy 'n negatiewe swangerskaptoets hê voordat jy SYROMAK 10 ODT begin neem.
Terwyl jy SYROMAK 10 ODT neem, moet jy 'n betroubare metode van voorbehoedmiddel gebruik om swangerskap te verhoed.
Vroue wat MIV-positief is moet nie hul babas borsvoed nie, want MIV-infeksie kan in borsmelk aan die baba oorgedra word.
Praat onmiddellik met jou dokter indien jy bevrywed, of dawaan dink dat jy is bevrywed.

Bestuur en gebruik van masjinerie
SYROMAK 10 ODT kan jou duiseling maak as ander newe-effekte by jou voorkom waarvan maak. Moet nie bestuur of masjinerie gebruik, tot tyd jy weet dat jy die geskiktheid verwerf nie.
Dit is nie altyd moontlik om te voorspel tot watter mate SYROMAK 10 ODT met jou duiseling of duiselige kan inmeng nie. Indien jy nie bewus bent dat jy nie bogenoemde aktiwiteite maak nie, totdat jy bewus is van die mate waarin SYROMAK 10 ODT jou affekteer nie.

Belangrike inligting oor sommige van die bestanddele van SYROMAK 10 ODT
Hierdie produk bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê dit is in wese 'natriumvry'.

3. Hoe om SYROMAK 10 ODT te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Gebruik altyd SYROMAK 10 ODT presies soos jou dokter dit aan jou voorgeskryf het. Vra vir jou dokter of apteker indien jy onseker is.

Die gewone dosis is:
Volwassenes:
- Die gewone dosis van SYROMAK 10 ODT is 50 mg (drie 10 mg dispergeerbare tablette), een keer per dag; of
- Vir MIV-infeksie wat weerstandbreekend teen ander medisyne soortgelyk aan SYROMAK 10 ODT is, is die gewone dosis van SYROMAK 10 ODT 50 mg (drie 10 mg dispergeerbare tablette), twee keer per dag.
- Jou dokter sal besluit oor die korrekte dosis van SYROMAK 10 ODT vir jou.

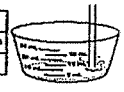
Kinders en adolessente:
Jou dokter sal besluit oor die korrekte dosis van SYROMAK 10 ODT vir jou kind, afhangende van die gewig van die kind.
- Kinders se dosis van 5 PYROMAK 10 ODT moet aangepas word soos wat hulle ouer word of gewig optel.
- Dit is die belangrik dat kinders beplande ontspreisiegroepe nakom.
- Vir kinders met 'n vuurvorm van swyfsiekte 4 weke oud en wat tussen 3 en 20 kg weeg, sal jou dokter op die korrekte dosis van SYROMAK 10 ODT besluit, afhangend van die gewig en ouderdom van jou kind.
- Indien tablette heel kan met water ingeskluk word, moet kinders nie meer as een tablet op 'n slag sluk nie, om sodoende die risiko van verstikking te verminder.

SYROMAK 10 ODT word nie gebruik word in kinders en adolessente met MIV-infeksie wat weerstandbreekend is wat is nie onder medisyne soortgelyk aan SYROMAK 10 ODT nie.

Metode van toediening
- Die dispergeerbare tablette kan in die water versper word, of heel ingesluk word met drinkwater.
- Wanneer dit versper word, sal die hoeveelheid water afhang van die aantal tablette wat voorgeskryf is. Die tablet(te) moet volledig versper word voordat dit ingeneem word.
- Moet nie die tablette kou of breek nie.
- SYROMAK 10 ODT kan net of sonder kos geneem word. Wanneer SYROMAK 10 ODT twee keer per dag geneem word, kan jou dokter jou aanraai om dit saam met kos te neem.
- Jy moet die dosis van medisyne gee binne 30 minute nadat jy die dosering voorbereid het, indien dit langer as 30 minute is, spoel die dosering weg en berei 'n nuwe dosis van die medisyne voor.

Gebruiksaanwysings:
Indien jou kind in staat is, en verkies om die tablette te sluk, kan jy die volgende stappe oorsien.
Stap 1 water:

Water Volume gids			
Aantal tablette	Halwe	1 Een en 'n halwe	2 Twee en 'n halwe
Volume water	5 ml	10 ml	



- Gebruik stroom drinkwater in die koppie in.
  Die vereiste volume gas hierbo toon die aanvaarbaar water wat benodig word vir die voorgeskrewe dosis.

Gebruik slegs drinkwater.
Moet die enige ander vloeistowwe of kos gebruik om die dosering voor te berei nie.
Hoe om die medisyne voor te berei:



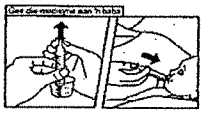
- Voeg die voorgeskrewe aantal tablet(te) by die water.
- Beweeg die koppie versigtig en vinnig, met 'n draaiende, sirkelvormige beweging, vir 1 tot 2 minute om die tablet(te) te versper. Die medisyne sal toetsel word. Wees versigtig om nie enige van die medisyne te mors nie.
- Maak seker dat die medisyne gereed is. Indien daar enige klonte van die tablet is, beweeg die koppie vinnig, met 'n draaiende, sirkelvormige beweging totdat dit weg is.

Indien jy enige hardeyne mors, maak die persoon skoon.
Gooi die res van die voorbereide medisyne weg en maak 'n nuwe dosis aan.
Jy moet die dosis van die medisyne gee, binne 30 minute nadat jy die dosering voorbereid het, indien dit langer as 30 minute is, spoel die dosering weg en berei 'n nuwe dosis van die medisyne voor.
Gee die medisyne:



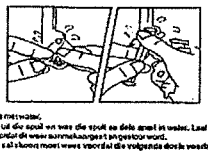
- Maak seker dat die kind regop sit. Gee al die voorbereide medisyne vir die kind.
- Voeg nog 5 ml drinkwater by die koppie, beweeg die koppie vinnig, met 'n draaiende, sirkelvormige beweging en gee dit aan die kind om te drink.
- Herhaal indien enige medisyne oorbly, om sodoende seker te maak dat die kind die volle dosis kry.

Gee die medisyne aan 'n baba:



- Plaas die punt van die spuit aan die voorbereide medisyne en trek al die medisyne in die spuit op deur die suier op te trek.
- Plaas die punt van die spuit teen die binne kant van die baba se wang. Druk die suier versigtig af en die dosis stadig te gee.
- Voeg nog 5 ml drinkwater by die koppie en beweeg die koppie vinnig, met 'n draaiende, sirkelvormige beweging. Trek die oorblywende medisyne in die spuit op en gee dit aan die baba om te drink.

Herhaal indien enige medisyne oorbly, om sodoende seker te maak dat die baba die volle dosis kry.
Gee tyd sodat die medisyne geslukt kan word.
Stelsmaak:
Maak die dosse nie itsma skoon:



- Was die koppie met water.
- Trek die water uit die spuit en was die spuit se dele apart in water. Laat die dele heelmaal droog word voordat die weer saamgevoeg word.

Alle gebruikte dele sal skoon moet wees voordat die volgende dosis voorbereid word.
Teenaanwysings
Teenaanwysings, en slegte spysvertering en sooibrand is bekend. Kan toe dat SYROMAK 10 ODT in jou liggaam opgeneem word en dit minder effektief maak.
Moet nie 'n teensuurmiddel neem tydens die 6 ure voordat jy SYROMAK 10 ODT neem, of vir ten minste 2 ure nadat jy dit geneem het nie.
Ander suurvorstgende middels soos ranitidien en omeprasol kan op dieselfde tyd as SYROMAK 10 ODT geneem word.
- Praat met jou dokter vir verdere advies oor die neem van suurvorstgende middels saam met SYROMAK 10 ODT.

Kalsiumaanvullings, yster aanvullings of multivitamiene
Kalsiumaanvullings, yster aanvullings of multivitamiene kan toe dat SYROMAK 10 ODT in jou liggaam opgeneem word en dit minder effektief maak.
Moet nie 'n kalsiumaanvulling, yster aanvulling of multivitamien neem tydens die 6 ure voordat jy SYROMAK 10 ODT neem, of vir ten minste 2 ure nadat jy dit geneem het nie.
- Praat met jou dokter vir verdere advies oor die neem van kalsiumaanvullings, yster aanvullings of multivitamiene saam met SYROMAK 10 ODT.

Indien jy die indruk kry dat die effek van SYROMAK 10 ODT te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer SYROMAK 10 ODT neem as wat jy behoort te neem.
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Mediese sorg mag nodig wees. Indien jy na 'n dokter of hospitaal moet gaan, neem die verpakking en hierdie inligtingsluk saam met jou.

Indien jy vergeet om SYROMAK 10 ODT te neem
Indien jy 'n dosis oorslaan, neem dit so gou as wat jy daarvan onthou, maar slaan dit binne 4 uur van jou volgende dosering is, slaan die dosis oor wat jy vergeet het en neem die volgende een op die gewone tyd. Gaan dan aan met jou behandeling, soos voorheen.
Moet die 'n dubbele dosering neem om vir vergete individuele dosisse op te maak nie.

Indien jy ophou om SYROMAK 10 ODT te neem
Neem SYROMAK 10 ODT vir so lank as wat jou dokter dit aanbeveel. Moet nie ophou, tensy jou dokter jou eersvat anders te doen sê.

4. Moontlike newe-effekte

SYROMAK 10 ODT kan newe-effekte hê.
Nie al die newe-effekte wat vir SYROMAK 10 ODT gerapporteer is, is in hierdie inligtingsluk ingesluk nie. Gou jou algemene gesondheid verslag al jy enige ongewone effekte ondervind terwyl jy SYROMAK 10 ODT gebruik, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, staak die gebruik van SYROMAK 10 ODT en sê onmiddellik jou dokter in, of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond vir keel, wat probleme kan veroorsaak om te sluk of asem te haal.
- uitslag of jeuk.
- koors

Hierdie is alles baie ernstige newe-effekte. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op SYROMAK 10 ODT gehad. Jy het moontlik dringende mediese sorg of hospitaalsorg nodig.

Lig onmiddellik jou dokter in of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende waarneem:
- braakspy.
- angina.
- veranderinge in die manier waarop jou hart klop, byvoorbeeld, as jy agterkom dat dit vinniger klop.
- snaakse asemhaling
- tekens van herhaalde infeksies soos koors of seer keel.
- minder urine as wat jy tot normaal is.
- vergeling van die vel en oë, donker urine en ongesteldheid wat simptome van lewerprobleme kan wees.

Hierdie is ernstige newe-effekte, Jy het moontlik dringende mediese sorg nodig.

Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereelde newe-effekte:
- hoofpyn, duiseligheid.
- ongewone drome, slaap, abnormale drome, depressie (voel hartseer), voel angstig.
- naarheid, diarree, braking, winde (vleiderigheid), boorstile, maagsmerte pyn.
- uitslag, insluitend kwaartuie letsies (bewegig deur bloedsetse).
- uitslag, jeuk.
- vermoeidheid.
- koorsverwante reaksies (verskynsels wat lei die spiere geproduseer word (bevestig deur laboratoriumtoetse)

Minder gereelde newe-effekte:
- droë huid.
- allergiese reaksies.
- swelling van die hande, voete, enkels, gesig, lippe en mond vir keel, wat probleme kan veroorsaak om te sluk of asem te haal.
- allergiese reaksies, insluitend hooggebouede inflammatoriese sindroom - 'n inflammatoriese toestand wat kan ontwikkel soos die immuunstelsel sterker word.
- selfmoordgedagtes (hoofsaaklik by pasiënte wat voorheen depressie of geestesgesondheids probleme gehad het).
- pyn en ongemak in die bulk.
- swelling van die lewer, lewerprobleme, verhoogde bilirubien - 'n stof wat deur die lewer geproduseer word (bevestig deur toetse).
- spier- en gewrigspyn

Frekwensie onbekend:
- toename in gewig

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingsluk genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingsluk genoem word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die "6.24 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: http://www.sahpra.org.za/Publication/Index6.
Deur newe-effekte te aan te meld, kan jy help om meer belyting rakende die veiligheid van SYROMAK 10 ODT te verskaf.

5. Hoe om SYROMAK 10 ODT te bewaar

Bewaar by of tussen 30°C (kamertemperatuur).
Hou die HDPE houer dig toe.
Stoor in die oorspronklike verpakking om omtrente toon vog te beskerm.
BEWAAR BUITE BEREIK VAN KINDERS
Moet nie in die badkamer bêre nie.
Moet nie na die vervaldatum, wat op die bottel aangedui word, gebruik nie.
Neem ongebruikte medisyne in die dreun of naaldeskade (bv. tablette) good nie.

6. Inhoud van die verpakking en ander inligting

Wat SYROMAK 10 ODT bevat
Die aktiewe bestanddeel is dolutegravirnatrium.
Bevat suiker (29,84 mg mannitol) en Vanoxter (1,20 mg sukraloset).
Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê dit is in wese 'natriumvry'.
Die ander bestanddele is:
Tabletkern bevat
Natriumstyrielsteenbreksel, krospovidoon, mannitol, mikrokristallyne sellulose, povinoon, verskillende mikrokristallyne sellulose, natriumstearylfumaraat, natriumlaurielsulfaatmengsel, sukrolose,
Deklaseerlaag bevat
Hipromellose, titaandioksied, macrogol, rooi yelerokkaid.

Hoe SYROMAK 10 ODT lyk en inhoud van die verpakking
Pienkbruinige, kapsuulvormige, filmgedekte tablette, met "K" en "1" aan die een kant gedruk, geskik vir inname, en breekbyn aan die aanderkant.
Die tablet kan in gelyke helftes verdeel word.

Inhoud van die verpakking:
HDPE houer
Tablette word verpak in 'n ronde wit HDPE houer met tuigemaak is met kinderbestande sluiting, of deurlopende of aanpuiking, met pulp en hitteseëlfoppring, met of sonder silikagel.
Vogabsorbeermiddel sluit 28's, 30's en 90's tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Sertifikaat van Registrasie
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kanodevan 1, Basaonia Corporate Park, Kanoperaan (Oos),
Cussonevrylaan 7, Basaonia Rock, Units 12,
Alberton, Suid-Afrika

Hierdie inligtingsluk is laas hersien in
14 JUNIE 2022

Registrasienommer
SYROMAK 10 ODT: 56/20.2.8/0119

Verdie eerse en teenstrekte Professionele Inligting
Die eerse en teenstrekte professionele inligting kan by hetps://medicinesproducts.co.za/ verkry word of deur 011 542 1168 te kontak

Die produk is verkrygbaar onder 'n lisensie van die Medicines Patent Pool
Die Produkte is nie vir toediening aan swangerand anders as Kinderpasiënte nie
Enige ander gebruik word nie gemagtig nie

360 mm

335 mm

PACKAGING RESEARCH & DEVELOPMENT

MACLEODS

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: SYROMAK 10 ODT (Dolutegravir Sodium Filmcoated Dispersible Tablets 10 mg)	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 GSM Bible paper	
7. Machine Layout No.: NA	8. Dimensions: 360 (L) x 335 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM04235601
11. Artwork has been made: Actual Size	12. Pharma code No.: 33285 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. File Name : X:\Dolutegravir\SA Private market\02\Dolutegravir 10 mg PIL -PM04235601.cdr
Approved By:	17. Location: Daman

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
11/10/23	Vanita Rajool	12/10/23	13/10/23	16/10/23	17/10/23

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - (Private Market)	PM04235601		

Front Side

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SYROMAK 10 ODT

Dolutegravir sodium 10.52 mg equivalent to dolutegravir 10 mg
Contains sugar (29.06 mg mannitol) & sweetener (1.20 mg sucralose)

Read all of this leaflet carefully before you start taking SYROMAK 10 ODT
Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
SYROMAK 10 ODT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **SYROMAK 10 ODT** is and what it is used for
2. What you need to know before you take **SYROMAK 10 ODT**
3. How to take **SYROMAK 10 ODT**
4. Possible side effects
5. How to store **SYROMAK 10 ODT**
6. Contents of the pack and other information

1. What SYROMAK 10 ODT is and what it is used for

SYROMAK 10 ODT contains dolutegravir sodium.

SYROMAK 10 ODT is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called integrase inhibitors (INIs).

SYROMAK 10 ODT is used to treat HIV (human immunodeficiency virus) infection in adults, adolescents and children in combination with other anti-retroviral medicines.

2. What you need to know before you take SYROMAK 10 ODT

Do not use SYROMAK 10 ODT:
- If you are hypersensitive (allergic) to dolutegravir or any of the other ingredients of **SYROMAK 10 ODT**
- if you are taking another medicine called dofetilide or pilsicainide (to treat heart conditions)
- if you have severe liver disease
- if you are in the first trimester of your pregnancy and if you are breastfeeding.
- if you (or your child) are taking another medicine called fampridine (also known as dalfampridine, used in multiple sclerosis).

Warnings and precautions
Take special care with **SYROMAK 10 ODT**
- If you develop a rash. Some people taking **SYROMAK 10 ODT** have had allergic reactions.
- if you get any symptoms of infection while you are taking **SYROMAK 10 ODT**:
  People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections (such as tuberculosis) flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.
- If you experience joint pain, stiffness and bone problems
- **Keep in touch with your doctor, and do not stop taking SYROMAK 10 ODT without your doctor's advice.**
  HIV can still be transmitted despite taking **SYROMAK 10 ODT. SYROMAK 10 ODT** does not cure HIV infection; it reduces the amount of virus in your body.
- **While you are taking SYROMAK 10 ODT, you will need regular blood tests.**
  For as long as you are taking **SYROMAK 10 ODT**, your doctor will arrange regular blood tests to check for side effects. There is more information about these side effects in this leaflet. See section 4.
- You need to know about important signs and symptoms to look out for while you (or your child, if they are the patient) are taking **SYROMAK 10 ODT.**
  Read the information in Section 4 of this leaflet.
- **Protect other people.**
  HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). **SYROMAK 10 ODT** will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:
  - o Use a condom when you have oral or penetrative sex.
  - o Do not risk blood transfer - for example, don't share needles.

Use in children and adolescents
Children
Do not give this medicine to children under 4 weeks of age, weighing less than 3 kg or with HIV infection that is resistant to other medicines similar to **SYROMAK 10 ODT.** The use of **SYROMAK 10 ODT** dispersible tablets in children under 4 weeks or weighing less than 3 kg has not yet been studied.
Children must keep planned doctor's appointments (see 'Children and adolescents' in Section 4 for more information).

Other medicines and SYROMAK 10 ODT
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
- Dofetilide or pilsicainide, to treat heart conditions.

Some medicines can affect how **SYROMAK 10 ODT** works or make it more likely that you will have side effects. These include:
- metformin, to treat diabetes
- medicines called antacids, to treat indigestion and heartburn. Do not take an antacid during the 6 hours before you take **SYROMAK 10 ODT**, or for at least 2 hours after you take
- calcium and iron supplements. Do not take a calcium or iron supplement during the 6 hours before you take **SYROMAK 10 ODT**, or for at least 2 hours after you take it
- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection
- rifampicin, to treat tuberculosis and other bacterial infections
- phenytoin and phenobarbitone, to treat epilepsy
- carbamazepine, to treat epilepsy and bipolar disorder
- St. John's wort, (Hypericum perforatum), a herbal remedy to treat depression.

Tell your doctor or pharmacist if you are taking any of these. Your doctor may decide to adjust your dose or that you need extra check-ups.

SYROMAK 10 ODT with food and drink and alcohol
SYROMAK 10 ODT can be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
You should not use **SYROMAK 10 ODT** during pregnancy.
Safe use during pregnancy and breastfeeding has not been established.
If you are of the age of taking pregnant, you should have a negative pregnancy test before you start taking **SYROMAK 10 ODT.**
While you are taking **SYROMAK 10 ODT** you must use a reliable method of contraception, to prevent pregnancy.
Women who are HIV-positive should not breastfeed their babies, because HIV infection can be passed on to the baby in breast milk.
Talk to your doctor immediately, if you are breastfeeding, or thinking about breastfeeding.

Driving and using machines
SYROMAK 10 ODT can make you dizzy and have other side effects that make you less alert. Do not drive or use machines unless you are sure you are not affected.
It is not always possible to predict to what extent **SYROMAK 10 ODT** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **SYROMAK 10 ODT** affects you.

Important information about some of the ingredients of SYROMAK 10 ODT
This product contains less than 1 mmi sodium (23 mg) per tablet that is to say is essentially 'sodium free'.

3. How to take SYROMAK 10 ODT

Do not share medicines prescribed for you with any other person.

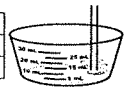
Always use **SYROMAK 10 ODT** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
The usual dose is:
Adults
- The usual dose of **SYROMAK 10 ODT** is 30 mg (three 10 mg dispersible tablets), once a day or
- For HIV infection that is resistant to other medicines similar to **SYROMAK 10 ODT**, the usual dose of **SYROMAK 10 ODT** is 30 mg (three 10 mg dispersible tablets), twice a day.
- Your doctor will decide on the correct dose of **SYROMAK 10 ODT** for you.

Children and adolescents:
Your doctor will decide on the correct dose of **SYROMAK 10 ODT** for your child, depending on the weight of the child.
- Children's dose of **SYROMAK 10 ODT** needs to be adjusted as they get older or gain weight.
- It is important therefore that children keep planned doctor's appointments.
- For children aged at least 4 weeks and weighing between 3 and 20 kg, your doctor will decide on the correct dose of **SYROMAK 10 ODT**, depending on the weight and age of your child.
- If swallowing tablets whole with water, children must not swallow more than one tablet at a time to reduce the risk of choking.

SYROMAK 10 ODT should not be used in children and adolescents with HIV infection that is resistant to other medicines similar to **SYROMAK 10 ODT.**
Method of administration
- The dispersible tablets may be dispersed in drinking water or swallowed whole with drinking water.
- When dispersed, the amount of water will depend on the number of tablets prescribed. The tablet(s) should be fully dispersed before swallowing.
- Do not chew or crush the tablets.
- **SYROMAK 10 ODT** can be taken with or without food. When **SYROMAK 10 ODT** is taken twice a day, your doctor may advise you to take with food.
- You must give the dose of medicine within 30 minutes of preparing the dose. If it has been more than 30 minutes wash the dose away and prepare a new dose of medicine.

Instructions for Use:
If your child is able and prefers to swallow the tablets, then you may skip the following steps
Pour water:

Water Volume Guide						
Number of tablets	Half	1	one and a half	2	Two and a half	3
Volume of water	5 mL		10 mL			



- Pour clean drinking water into the cup.
  The water volume guide above shows the amount of water needed for the prescribed dose.

Use drinking water only.
Do not use any other drink or food to prepare the dose.
How to prepare the medicine:



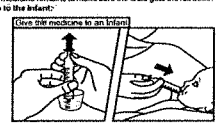
- Add the prescribed number of tablet(s) to the water.
- Swirl the cup gently for 1 to 2 minutes to disperse the tablet(s). The medicine will become cloudy. Take care not to spill any of the medicine.
- Check that the medicine is ready. If there are any lumps of tablet swirl the cup until they are gone.

If you spill any medicine, clean up the spill.
Throw away the rest of the prepared medicine and make a new dose.
You must give the dose of medicine within 30 minutes of preparing the dose. If it has been more than 30 minutes wash the dose away and prepare a new dose of medicine.
Giving the medicine:



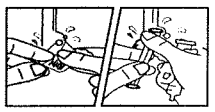
- Make sure that the child is upright. Give all the prepared medicine to the child
- Add another 5 ml of drinking water to the cup, swirl and give it all to the child.
- Repeat if any medicine remains to make sure the child gets the full dose.

Give the medicine to the infant:



- Place the tip of the syringe into the prepared medicine and draw up all the medicine into the syringe by pulling up on the plunger.
- Place the tip of the syringe against the inside of the infant's cheek. Gently push down the plunger to give the dose slowly.
- Add another 5 mL of drinking water to the cup and swirl. Draw up the remaining medicine into the syringe and give it all to the infant.

Repeat if any medicine remains to make sure the infant gets the full dose.
Allow time for the medicine to be swallowed.
Cleaning:
Clean the dosing items:



- Wash the cup with water.
- Pull the plunger out of the syringe and wash the syringe parts separately in water. Allow parts to dry completely before reassembling and storing.

All used parts will need to be clean before preparing the next dose.
Antacid medicines
Antacids, to treat indigestion and heartburn, can stop **SYROMAK 10 ODT** being absorbed into your body and make it less effective.
Do not take an antacid during the 6 hours before you take **SYROMAK 10 ODT**, or for at least 2 hours after you take it.
Other acid-lowering medicines like ranitidine and omeprazole can be taken at the same time as **SYROMAK 10 ODT.**
- Talk to your doctor for further advice on taking acid-lowering medicines with **SYROMAK 10 ODT.**

Calcium supplements, iron supplements or multivitamins
Calcium supplements, iron supplements or multivitamins can stop **SYROMAK 10 ODT** being absorbed into your body and make it less effective.
Do not take a calcium supplement, iron supplement or multivitamin during the 6 hours before you take **SYROMAK 10 ODT**, or for at least 2 hours after you take it.
- Talk to your doctor for further advice on taking calcium supplements, iron supplements or multivitamins with **SYROMAK 10 ODT.**

If you have the impression that the effect of **SYROMAK 10 ODT** is too strong or too weak, talk to your doctor or pharmacist.

If you take more SYROMAK 10 ODT than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Medical attention may be necessary. If you have to go to a doctor or hospital, take the pack and this leaflet with you.

If you forget to take SYROMAK 10 ODT
If you miss a dose, take it as soon as you remember, but if it is within 4 hours of your next dose, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.
Do not take a double dose to make up for a missed dose.

If you stop taking SYROMAK 10 ODT
Take **SYROMAK 10 ODT** for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

SYROMAK 10 ODT can have side effects.
Not all side effects reported for **SYROMAK 10 ODT** are included in this leaflet. Should your general health worsen or if you experience any unknown effects while taking **SYROMAK 10 ODT**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking SYROMAK 10 ODT and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to **SYROMAK 10 ODT.** You may need urgent medical attention or hospitalisation.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- chest pain,
- angina,
- changes in the way your heartbeats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects
- headache, dizziness,
- inability to sleep, abnormal dreams, depression (feeling sad), feeling anxious
- Nausea, diarrhoea, vomiting, wind (flatulence), upper abdominal pain
- abnormal liver function tests (confirmed through blood tests)
- rash, itching
- feeling tired
- increase in creatine phosphokinase - enzymes produced in the muscles (confirmed through lab tests)

Less frequent side effects
- dry cough,
- muscle cramps,
- flatulence or wind,
- diarrhoea,
- loss of appetite
- allergic reactions, immune reconstitution inflammatory syndrome - an inflammatory condition which may develop as the immune system becomes stronger
- suicide thoughts (mainly in patients who have had depression or mental health problems before)
- pain and discomfort in the abdomen
- inflammation of the liver, liver problems, increased bilirubin - a substance produced by the liver (confirmed through tests)
- muscle and joint pain

Frequency unknown
- Weight gain

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04** Adverse **D**rug **R**eaction **R**eporting **F**orm", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **SYROMAK 10 ODT.**

5. How to store SYROMAK 10 ODT

Store at or below 30 °C (room temperature).
Keep the HDPE container tightly closed.
Store in the original package in order to protect from moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What SYROMAK 10 ODT contains
The active ingredient is dolutegravir sodium.
Contains sugar (29.06 mg mannitol) & sweetener (1.20 mg sucralose)
This medicine contains less than 1 mmol sodium (23 mg) per tablet that is to say is essentially 'sodium free'.
Other ingredients are:
Tablet core contains
Calcium sulphate dihydrate, crospovidone, mannitol, microcrystalline cellulose, povidone, silicified microcrystalline cellulose, sodium starch glycolate, sodium stearyl fumarate, strawberry cream flavor, sucralose
Coating material contains
Hypromellose, titanium dioxide, macrogol, iron oxide red.

What SYROMAK 10 ODT looks like and contents of the pack
Pink colored, caplet shaped, film coated tablets, debossed "K" and "1" separated by breakline on one side and breakline on other side.
The tablet can be divided into equal halves.

Contents of the pack:
HDPE container
Tablets are packed in a round white HDPE container closed with child resistant closure or continuous thread closure with pulp and heat seal liner with or without silica gel.
Pack sizes include 28's, 30's and 90's tablets.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in
14 JUNE 2022

Registration number
SYROMAK 10 ODT: 56/20.2.8/0719

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://macleodssapproducts.co.za/ or contact 011 682 1189

The Product has been manufactured under a license from the Medicines Patent Pool
The Products are not for administration to anyone other than Child Patients
Any other use is not authorized

SYROMAK 10 ODT
PM04235501

335 mm

360 mm

Front Side

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S4

SYROMAK 10 ODT
Dolutegravirnatrium 10,52 mg ekwivalent aan 10 mg dolutegravir
Bevat suiker (29,08 mg mannitol) en Versoeter (1,20 mg sukralose).

Lees hierdie inligtingstuk aandagtig voordat jy SYROMAK 10 ODT begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- **SYROMAK 10 ODT** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat in hierdie inligtingstuk is
1. Wat **SYROMAK 10 ODT** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **SYROMAK 10 ODT** neem
3. Hoe om **SYROMAK 10 ODT** te neem
4. Moontlike newe-effekte
5. Hoe om **SYROMAK 10 ODT** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat SYROMAK 10 ODT is en waarvoor dit gebruik word

SYROMAK 10 ODT bevat dolutegravirnatrium.
SYROMAK 10 ODT is 'n tipe medisyne wat bekend staan as 'n anti-retrovirale middel. Dit behoort aan 'n groep medisyne wat integrase-inhibeerders (INI's) genoem word.

SYROMAK 10 ODT word gebruik om MIV (menslike immuniteitsgebrekvirus) infeksie in volwassenes, adolessente en kinders te behandel in kombinasie met ander anti-retrovirale middels.

2. Wat jy behoort te weet voordat jy SYROMAK 10 ODT neem

Moet nie SYROMAK 10 ODT gebruik nie:
- indien jy hipersensitief (allergies) vir dolutegravir of enige van die ander bestanddele van **SYROMAK 10 ODT** is
- indien jy 'n ander middel genaamd dofetilied of pilsikalenied neem (om hartkloptempo te behandel)
- indien jy ernstige lewersiekte het
- indien jy in die eerste trimester van jou swangerskap is en indien jy borsvoed
- indien jy (of jou kind) 'n ander medisyne genaamd fampridien neem (ook bekend as dalfampridien, gebruik in veelvuldige sklerose).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **SYROMAK 10 ODT**
- indien jy 'n uitslag ontwikkel. Sommige mense wat **SYROMAK 10 ODT** neem, het allergiese reaksies gehad.
- indien jy enige simptome van infeksie kry terwyl jy **SYROMAK 10 ODT** neem:
  Mense met gevorderde MIV-infeksie (VIGS) het swak immuunstelsels en is meer geneig om ernstige infeksies (opportunistiese infeksies) te ontwikkel. Wanneer hierdie mense met behandeling begin, kan hulle veral dat ou, verstekte infeksies (soos tuberkulose) opvlam, wat tekens en simptome van inflammasie veroorsaak. Hierdie simptome word waarskynlik veroorsaak deur die liggaam se immuunstelsel wat sterker word, sodat die liggaam hierdie infeksies begin beveg.
- indien jy gewrigspyn, styfheid en beenprobleme ervaar.
- **Bly in kontak met jou dokter, en moet nie ophou om SYROMAK 10 ODT te neem sonder jou dokter se advies nie,**
  MIV kan steeds oorgedra word ondanks die neem van **SYROMAK 10 ODT. SYROMAK 10 ODT** genees nie MIV-infeksie nie; dit verminder die hoeveelheid virus in jou liggaam.
- **Terwyl jy SYROMAK 10 ODT gebruik, sal jy gereelde bloedtoetse moetig hê.**
  Vir sekere sal wat jy **SYROMAK 10 ODT** neem, sal jou dokter gereelde bloedtoetse reël om te kyk vir newe-effekte. Daar is meer inligting oor hierdie newe-effekte in hierdie inligtingstuk, Sien afdeling 4.
- Jy moet weet van beiangrike tekens en simptome waarvoor jy moet oplet terwyl jy (of jou kind, indien hulle die pasiënt is) **SYROMAK 10 ODT** neem.
  Lees die inligting in Afdeling 4 van hierdie inligtingstuk.
- **Beskerm ander mense.**
  MIV-infeksie word versprei deur seksuele kontak met iemand wat die infeksie het, of deur die oordrag van besmette bloed (byvoorbeeld deur inspuitings naalde te deel). **SYROMAK 10 ODT** sal nie keer dat jy MIV-infeksie aan ander mense oordra nie. Om ander mense te beskerm teen besmetting met MIV:
  - Gebruik 'n kondoom wanneer jy orale of penetrerende seks het,
  - Moet nie oordrag van bloed waag nie – moet byvoorbeeld nie naalde deel nie.

Gebruik in kinders en adolessente
Kinders
Moet nie hierdie medisyne gee aan kinders jonger as 4 weke oud, wat minder as 3 kg weeg of met MIV-infeksie wat weerstandbiedend is teen ander medisyne soortgelyk aan **SYROMAK 10 ODT** nie. Die gebruik van **SYROMAK 10 ODT** dispergeerbare tablette in kinders jonger as 4 weke oud of wat minder as 3 kg weeg, is nog nie bestudeer nie.
Kinders moet beplande dokters afsprake nakom (sien 'Kinders en adolessente' in Afdeling 4 vir meer inligting).

Ander medisyne en SYROMAK 10 ODT
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem, (Dit sluit alle komplementêre of tradisionele medisyne in.)
- Dofetilied of pilsikalenied, vir die behandeling van hartloestande.

Sommige medisyne kan beïnvloed hoe **SYROMAK 10 ODT** werk of dit meer waarskynlik maak dat jy newe-effekte sal hê. Dit sluit in:
- metformien, om diabetes te behandel
- "medisyne wat teensuurmiddels genoem word, om slegte spysvertering en sooibrand te behandel. Moet nie 'n teensuurmiddel neem gedurende die 6 uur voordat jy **SYROMAK 10 ODT** neem nie, of vir ten minste 2 uur nadat jy dit geneem het
- kalsium- en ysteraanvullings. Moet nie 'n kalsium- of ysteraanvulling neem gedurende die 6 uur voordat jy **SYROMAK 10 ODT** neem nie, of vir ten minste 2 uur nadat jy dit geneem het nie
- efavirenz, efavirenz, fosamprenavir/ritonavir, nevirapien of lopinavir/ritonavir om MIV-infeksie te behandel
- rifampisien, om tuberkulose en ander bakteriële infeksies te behandel
- fenitoïen en fenobarbitaan, om epilepsie te behandel
- karbamasepien, om epilepsie en bipolêre versteuring te behandel
- St. Janskruid, (*Hypericum perforatum*), 'n kruiemiddel om depressie te behandel.

Vertel jou dokter of apteker indien jy enige van hierdie gebruik. Jou dokter kan besluit om jou dosis aan te pas of dat jy ekstra ondersoeke benodig.

SYROMAK 10 ODT saam met kos en vloeistowwe en alkohol
SYROMAK 10 ODT kan met of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om 'n baba te hê, vra jou dokter of apteker vir advies voordat jy hierdie medisyne neem.
Jy moet nie **SYROMAK 10 ODT** tydens swangerskap gebruik nie.
Veilige gebruik tydens swangerskap en borsvoeding is nie vasgestel nie.
Indien jy oud genoeg is om swanger te kan raak, moet jy 'n negatiewe swangerskapstoets hê voordat jy **SYROMAK 10 ODT** begin neem.
Terwyl jy **SYROMAK 10 ODT** neem, moet jy 'n betroubare metode van voorbehoeding gebruik om swangerskap te verhoed.
Vroue wat MIV-positief is moet nie hul babas borsvoed nie, want MIV-infeksie kan in borsmelk aan die baba oorgedra word.
Praat onmiddellik met jou dokter indien jy borsvoed, of daaraan dink om te borsvoed.

Bestuur en gebruik van masjinerie
SYROMAK 10 ODT kan jou duiseling maak en ander newe-effekte hê wat jou minder waaksaam maak. Moet nie bestuur of masjiene gebruik, tensy jy seker is dat jy nie geaffekteer word nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **SYROMAK 10 ODT** met jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie by bogenoemde aktiwiteite betrokke raak totdat jy bewus is van die mate waarin **SYROMAK 10 ODT** jou affekteer nie.

Belangrike inligting oor sommige van die bestanddele van SYROMAK 10 ODT
Hierdie produk bevat minder as 1 mmol natrium (23 mg) per tablet. dit wil sê dit is in wese 'natriumvry'.

3. Hoe om SYROMAK 10 ODT te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie

Gebruik altyd **SYROMAK 10 ODT** presies soos jou dokter dit aan jou voorgeskryf het. Vra vir jou dokter of apteker indien jy onseker is.

Die gewone dosis is:
Volwassenes:
- Die gewone dosis van **SYROMAK 10 ODT** is 30 mg (drie 10 mg dispergeerbare tablette), een keer per dag; of
- Vir MIV-infeksie wat weerstandbiedend lean ander medisyne soortgelyk aan **SYROMAK 10 ODT** is, is die gewone dosis van **SYROMAK 10 ODT** 30 mg (drie 10 mg dispergeerbare tablette), twee keer per dag.
- Jou dokter sal besluit oor die korrekte dosis van **SYROMAK 10 ODT** vir jou.

Kinders en adolessente:
Jou dokter sal besluit oor die korrekte dosis van **SYROMAK 10 ODT** vir jou kind, afhangende van die gewig van die kind.
- Kinders se dosis van **SYROMAK 10 ODT** moet aangepas word soos wat hulle ouer word of gewig optel.
  - Dit is dus belangrik dat kinders beplande doktersafsprake nakom.
- Vir kinders met 'n ouderdom van menstens 4 weke oud en wat tussen 3 en 20 kg weeg, sal jou dokter op die korrekte dosis van **SYROMAK 10 ODT** besluit, afhangend van die gewig en ouderdom van jou kind.
- Indien tablette heel saam met water ingesluk word, moet kinders nie meer as een tablet op 'n slag sluk nie, om sodoende die risiko van verstikking te verminder,

SYROMAK 10 ODT moet nie gebruik word in kinders en adolessente met MIV-infeksie wat weerstandbiedend is teen ander medisyne soortgelyk aan **SYROMAK 10 ODT** nie.

Metode van toediening
- Die dispergeerbare tablette kan in drinkwater versprei word, of heel ingesluk word met drinkwater,
- Wanneer dit versprei word, sal die hoeveelheid water afhang van die aantal tablette wat voorgeskryf is. Die tablet(te) moet volledig versprei word voordat dit ingesluk word.
- Moet nie die tablette kou of fynmaak nie,
- **SYROMAK 10 ODT** kan met of sonder kos geneem word, Wanneer **SYROMAK 10 ODT** twee keer per dag geneem word, kan jou dokter jou aanraai om dit saam met kos te neem.
- Jy moet die dosis van medisyne gee binne 30 minute nadat jy die dosering voorbereí het, Indien dit langer as 30 minute is, spoel die dosering weg en bereí 'n nuwe dosis van die medisyne voor.

Gebruiksaanwysings:
Indien jou kind in staat is, en verkies om die tablette te sluk, kan jy die volgende stappe oorslaan
Stik water:

Water Volume gids				
Aantal tablette	Halwe	1	Een en 'n halwe	2	Twee en 'n halwe	3
Volume water	5 mL		10 mL	



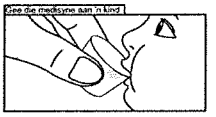
- Skink skoon drinkwater in die koppie in.
  Die water volume gids hierbo toon die hoeveelheid water wat benodig word vir die voorgeskrewe dosis.

Gebruik slegs drinkwater.
Moet nie enige ander vloeistowwe of kos gebruik om die dosering voor te berei nie.
Hoe om die medisyne voor te berei:



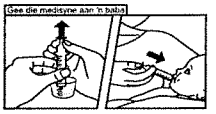
- Voeg die voorgeskrewe aantal tablet(te) by die water,
- Beweeg die koppie versigtig en vinnig, met 'n draaiende, sirkelvormige beweging, vir 1 tot 2 minute om die tablet(te) te versprei. Die medisyne sal troebel word. Wees versigtig om nie enige van die medisyne te mors nie.
- Maak seker dat die medisyne gereed is. Indien daar enige klonte van die tablet is, beweeg die koppie vinnig, met 'n draaiende, sirkelvormige beweging totdat dit weg is.

Indien jy enige medisyne mors, maak die gemors skoon.
Gooi die res van die voorbereide medisyne weg en maak 'n nuwe dosis aan.
Jy moet die dosis wat die medisyne gee, binne 30 minute nadat jy die dosering voorbereí het. Indien dit langer as 30 minute is, spoel die dosering weg en bereí 'n nuwe dosis van die medisyne voor.
Gee die medisyne:



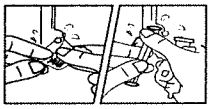
- Maak seker dat die kind regop is. Gee al die voorbereide medisyne vir die kind.
- Voeg nog 5 ml drinkwater by die koppie, beweeg die koppie vinnig, met 'n draaiende, sirkelvormige beweging, en gee dit alles vir die kind,
- Herhaal indien enige medisyne agterbly, om sodoende seker te maak dat die kind die volle dosis kry.

Gee die medisyne aan 'n baba:



- Plaas die punt van die spuit in die voorbereide medisyne en trek al die medisyne in die spuit op deur die suier op te trek,
- Plaas die punt van die spuit teen die binnekant van die baba se wang. Druk die suier versigtig af om die dosis stadig te gee.
- Voeg nog 5 mL drinkwater by die koppie en beweeg die koppie vinnig, met 'n draaiende, sirkelvormige beweging. Trek die oortollvende medisyne in die spuit op en gee dit alles vir die baba.

Herhaal indien enige medisyne agterbly, om sodoende seker te maak dat die baba die volle dosis kry.
Gee tyd sodat die medisyne geskluk kan word.
Skoonmaak:
Maak die doseer items skoon:



- Was die koppie met water,
- Trek die suier uit die spuit en was die spuit se dele apart in water. Laat die dele heeltemal droog word voordat dit weer aanmekaargesit en gestoor word.

Alle gebruikte dele sal skoon moet wees voordat die volgende dosis voorbereí word.
Teensuurmiddels
Teensuurmiddels, om slegte spysvertering en sooibrand te behandel, kan keer dat **SYROMAK 10 ODT** in jou liggaam opgeneem word en dit minder effektief maak.
Moet nie 'n teensuurmiddel neem tydens die 6 ure voordat jy **SYROMAK 10 ODT** neem, of vir ten minste 2 ure nadat jy dit geneem het nie.
Ander suurverlagende middels soos ranitidien en omeprasool kan op dieselfde tyd as **SYROMAK 10 ODT** geneem word,
- Praat met jou dokter vir verdere advies oor die neem van suurverlagende middels saam met **SYROMAK 10 ODT.**

Kalsiumaanvullings, ysteraanvullings of multivitamiene
Kalsiumaanvullings, ysteraanvullings of multivitamiene kan keer dat **SYROMAK 10 ODT** in jou liggaam opgeneem word en dit minder effektief maak.
Moet nie 'n kalsiumaanvulling, ysteraanvulling of multivitamien neem tydens die 6 ure voordat jy **SYROMAK 10 ODT** neem, of vir ten minste 2 ure nadat jy dit geneem het nie.
- Praat met jou dokter vir verdere advies oor die neem van kalsiumaanvullings, ysteraanvullings of multivitamiene saam met **SYROMAK 10 ODT**

Indien jy die indruk kry dat die effek van **SYROMAK 10 ODT** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer SYROMAK 10 ODT neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker, Indien nie een beskikbaar is nie, kontak die naeste hospitaal of gifbeheersentrum,
Medisyne aandag mag nodig wees. Indien jy na 'n dokter of hospitaal moet gaan, neem die verpakking en hierdie inligtingstuk saam met jou.

Indien jy vergeet om SYROMAK 10 ODT te neem
Indien jy 'n dosis oorslaan, neem dit so gou as wat jy daarvan onthou, maar indien dit binne 4 uur van jou volgende dosering is, slaan die dosis oor wat jy vergeet het en neem die volgende een op die gewone tyd. Gaan dan aan met jou behandeling, soos voorheen.
Moet nie 'n dubbele dosering neem om vir vergete individuele dosisse op te maak nie

Indien jy ophou om SYROMAK 10 ODT te neem
Neem **SYROMAK 10 ODT** vir so lank as wat jou dokter dit aanbeveel. Moet nie ophou, tensy jou dokter jou aanraai om dit te doen nie,

4. Moontlike newe-effekte

SYROMAK 10 ODT kan newe-effekte hê.
Nie al die newe-effekte wat vir **SYROMAK 10 ODT** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verslag of jy enige ongewenste effekte ondervind terwyl jy **SYROMAK 10 ODT** gebruik, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, staak die gebruik van SYROMAK 10 ODT en lig onmiddellik jou dokter in, of gaan na die ongevalle afdeling van jou naeste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- uitslag of jeuk,
- ßuiu

Hierdie is allles baie ernstige newe-effekte, Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **SYROMAK 10 ODT** gehad. Jy het moontlik dringende mediese aandag of hospitaalsasie nodig.

Lig onmiddellik jou dokter in of gaan na die ongevalle afdeling van jou naaste hospitaal Indien jy enige van die volgende waarneem:
- borskaspyn,
- angina,
- veranderinge in die manier waarop jou hart klop, byvoorbeeld, as jy agterkom dat dit vinniger klop,
- moeilike asemhaling
- tekens van herhaalde infeksies soos koors of seer keel.
- minder urlene as wat vir jou normaal is,
- vergeling van die vel en oë, donker urlene en moegheid wat simptome van lewerprobleme kan wees,

Hierdie is ernstige newe-effekte, **Jy het moontlik dringende mediese aandag nodig.**

Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereelde newe-effekte:
- hoofpyn, duiseligheid,
- onwelheid om te slaap, abnormale drome, depressie (voel hartseer), voel angstig,
- naarheid, diarree, braking, winde (winderigheid), boonste abdominale pyn,
- abnormale lewerfunksietoetse (bevestig deur bloedtoetse),
- uitslag, jeuk,
- voel moeg,
- toename in kreatienfosfokinase - ensieme wat in die spiere geproduseer word (bevestig deur laboratoriumtoetse)

Minder gereelde newe-effekte:
- droë hoes,
- spierkrampe,
- wenderigheid of winde,
- diarree,
- verfiets aan eelks,
- allergiese reaksies, immuun heropgeboude inflammatoriese sindroom - 'n inflammatoriese toestand wat kan ontwikkel soos die immuunstelsel sterker word,
- selfmoordgedagtes (hoofsaaklik in pasiënte wat voorheen depressie of geestesgesondheids probleme gehad het),
- pyn en ongemak in die bulk,
- ontsteking van die lewer, lewerprobleme, verhoogde bilirubien - 'n stof wat deur die lewer geproduseer word (bevestig deur toetse),
- spier- en gewrigspyn

Frekwensie onbekend:
- Toename in gewig

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk genoem word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van **SYROMAK 10 ODT** te verskaf.

5. Hoe om SYROMAK 10 ODT te bewaar

Bewaar by of benede 30°C (kamertemperatuur).
Hou die HDPE houer dig toe.
Stoor in die oorspronklike verpakking om sodoende lean vog te beskerm.
BEWAAR BUITE BEREIK VAN KINDERS
Moet nie in die badkamer bêre nie,
Moet nie na die vervaldatum, wat op die bottel aangedui word, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker,
Moet nie ongebruikte medisyne in die dreín of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die verpakking en ander inligting

Wat SYROMAK 10 ODT bevat
Die aktiewe bestanddeel is dolutegravirnatrium,
Bevat suiker (29,08 mg mannitol) en Versoeter (1,20 mg sukralose).
Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê dit is in wese 'natriumvry'.
Die ander bestanddele is
Tabletkern bevat
Kalsiumsulfaatdihidraat, kruispovidoon, mannitol, mikrokristallyne sellulose, povidoon, versiliseerde mikrokristallyne sellulose, natriumstyselglikolaat, natriumstearielfumaraat, aarbeiroomgeur, sukralose.
Dekmateriaal bevat
Hipromellose, titaandioksied, makrogol, rooi ysteroksied.

Hoe SYROMAK 10 ODT lyk en inhoud van die verpakking
Pienkkleurige, kapsuulvormige, filmbedekte tablette, met "K" en "1" aan die een kant gedruk, geskei deur breeklyn, en breeklyn aan die ander kant.
Die tablet kan in gelyke helftes verdeel word.

Inhoud van die verpakking:
HDPE houer
Tablette word verpak in 'n ronde wit HDPE houer wat toegemaak is met kinderbestande sluiting, of deurlopende draadsluiting, met pulp en hitieseëlvoering, met of sonder silikagel.
Verpakkingsgroottes sluit 28's, 30's en 90's tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Sertifikaat van Registrasie
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cassonia-vlaan 1, Bassonia Rock, Uitkr. 12,
Alberton, Suid-Afrika.

Hierdie inligtingstuk is laas hersien in
14 JUNIE 2022

Registrasienommer
SYROMAK 10 ODT: 56/20.2.8/0719

Vir die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan by https://macleodssaproducts.co.za/ verkry word of deur 011 682 1169 te kontak

De produk is vervaardig onder 'n lisensie van die Medicines Patent Pool
Die Produkte is ras vir toediening aan enigiemand anders as Kinderpasiënte nie
Enige ander gebruik word nie gemagtig nie

360 mm

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: SYROMAK 10 ODT (Dolutegravir Sodium Filmcoated Dispersible Tablets 10 mg)	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 GSM Bible paper	
7. Machine Layout No.: NA	8. Dimensions: 360 (L) x 335 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM04235601
11. Artwork has been made: Actual Size	12. Pharma code No.: 33285 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. File Name : X:\Dolutegravir\SA Private market\02\Dolutegravir 10 mg PIL -PM04235601.cdr
Approved By:	17. Location: Daman

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
	Vanita Rajool				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - (Private Market)	PM04235601		

(Back page)

Checklist

The Respective departmental heads are responsible for verification and approval. Responsibilities covered under this, but not restricted to are:

Artwork for: New / Existing product
PM04235601– PATIENT INFORMATION LEAFLET- SYROMAK 10 ODT(DOLUTEGRAVIR SODIUM FILMCOATED DISPERSIBLE TABLETS 10MG) (SOUTH AFRICA - PRIVATE MARKET)

Department	Responsibilities	Parameters	Remarks ('✓', '×'or NA)
Packaging Research and Development	Dimensional details and Code details.	Dimensions	✓
		Design	—
		Colour	✓
		Barcode/NDC no	—
		Item code	✓
		Pharma code	✓
Marketing	Design	Colour	
		Text	
		Design	
		Other (specific)	
Quality Control	Verifying the text matter,Label claim and Dimensions	Text	✓
		Label Claim	✓
		Dimensions	✓
		Code	✓
Quality Assurance	Verifying the text matter, Verifying the Label claim as per granted License, Checking Manufacturing License Number, Verifying the Legal requirements.	Text	✓
		Label Claim	✓
		Mfg. Lic. No.	✓
		Mfg. Address	✓
		Others (specific)	NA
Production	Availability of changeparts and overcoding space	Over coding space	NA
		Availability of change parts.	✓
		Dimensions	✓
		Availability of Lic.	NA
RAD	Verifying the text matter, Verifying the Label claim and Regulatory requirements	Text	✓
		Label Claim	✓
		Others (specific)	—
Medical services	Verifying the text matter, Verifying the Label claim	Text	
		Label Claim	
		Others (specific)	