Front Side

335 mm

260 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

MACSELTA 75 mg CAPSULES
Oseltamivir phosphate 75 mg
Sugar free

Read all of this leaflet carefully before you start taking MACSELTA 75 mg CAPSULES
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MACSELTA 75 mg CAPSULES** have 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 **MACSELTA 75 mg CAPSULES** is and what it is used for
2. What you need to know before you take **MACSELTA 75 mg CAPSULES**
3. How to take **MACSELTA 75 mg CAPSULES**
4. Possible side effects
5. How to store **MACSELTA 75 mg CAPSULES**
6. Contents of the pack and other information

1. What MACSELTA 75 mg CAPSULES is and what it is used for

MACSELTA 75 mg CAPSULES is used for adults, adolescents and children older than 1 year who have had flu symptoms for 2 days or less. **MACSELTA 75 mg CAPSULES** is also used to prevent some types of flu in adults and children (older than 1 year of age) when they have spent time with someone who has the flu or when there is a flu outbreak.
PANDEMIC USE:
MACSELTA 75 mg CAPSULES is indicated for the treatment of infants 6-12 months of age during a pandemic influenza outbreak only and not for endemic (seasonal) influenza use.
MACSELTA 75 mg CAPSULES works by stopping the spread of the flu virus in the body. **MACSELTA 75 mg CAPSULES** helps shorten the time that flu symptoms such as a stuffy or runny nose, sore throat, cough, muscle or joint aches, tiredness, headache, fever, and chills last. **MACSELTA 75 mg CAPSULES will** not prevent bacterial infections, which may occur as a complication of the flu.

2. What you need to know before you take or give MACSELTA 75 mg CAPSULES

Do not take or give MACSELTA 75 mg CAPSULES:
- If you are allergic (*hypersensitive*) to oseltamivir or any of the other ingredients of **MACSELTA 75 mg CAPSULES**, listed in section 6.

Warnings and precautions
Take special care with **MACSELTA 75 mg CAPSULES**:
- Some people using **MACSELTA 75 mg CAPSULES** have had side effects of sudden confusion, delirium, hallucinations, unusual behaviour, or self-injury. These symptoms have occurred most often in children. Anyone using **MACSELTA 75 mg CAPSULES** should be watched closely for signs of confusion or unusual behavior. Call your doctor at once if you or your child using **MACSELTA 75 mg CAPSULES** have any of these symptoms.
- Ask your doctor if you should receive a flu vaccination each year. **MACSELTA 75 mg CAPSULES** does not take the place of a yearly flu vaccine. It is recommended that an annual flu shot be taken to help protect you each year from new strains of influenza virus.
- Inform your doctor if you have problems with your kidneys. If so, your dose of **MACSELTA 75 mg CAPSULES** may need adjustment.

Other medicines and MACSELTA 75 mg CAPSULES
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
The following medicine is particularly important:
- probenecid (used to treat gout)

MACSELTA 75 mg CAPSULES with food and drink:
MACSELTA 75 mg CAPSULES can be taken with or without food. Taking **MACSELTA 75 mg CAPSULES** with food can reduce the chance of feeling or being sick (nausea or vomiting).

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **MACSELTA 75 mg CAPSULES.**
- Do not take **MACSELTA 75 mg CAPSULES** if you are pregnant. Inform your doctor immediately if you are pregnant or intend to become pregnant.
- Do not breastfeed if you are taking **MACSELTA 75 mg CAPSULES.**

Driving and using machines
MACSELTA 75 mg CAPSULES may cause side effects such as dizziness and visual disturbances, if these occur, your ability to drive or use machines may be impaired.

3. How to take MACSELTA 75 mg CAPSULES

Do not share medicines prescribed for you with any other person.
Always take or give **MACSELTA 75 mg CAPSULES** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
If you have the impression that the effect of **MACSELTA 75 mg CAPSULES** is too strong or too weak, talk to your doctor or pharmacist.
The usual dose in adults is:
For treating flu:
Treatment should begin within the first or second day of onset of symptoms of influenza.
Adults and adolescents older than 13 years: take one **MACSELTA 75 mg CAPSULES** twice daily for 5 days. It is usually convenient to take one dose in the morning and one in the evening. It is important to complete the whole 5-day course, even if you start to feel better quickly.
Children older than 8 years or weighing more than 40 kg who are able to swallow capsules, should be given one **MACSELTA 75 mg CAPSULES** twice daily.

For preventing flu or after being exposed to an infected person:
Treatment should begin within two days of exposure.
Adults and adolescents older than 13 years: take one **MACSELTA 75 mg CAPSULES** once daily for 10 days.
Children weighing more than 40 kg who are able to swallow capsules, should be given one **MACSELTA 75 mg CAPSULES** once daily for 10 days.
Treatment may continue for up to 6 weeks during a community outbreak of Influenza.

People who find it hard to take capsules: you can make a liquid form of **MACSELTA 75 mg CAPSULES** from these capsules at the pharmacy or at home
The dose is the same for treating or preventing flu. The difference is how often it is given.
Making liquid MACSELTA 75 mg CAPSULES at home
If you have the right capsule strength for the dose needed (a 75 mg dose), you will open the capsule and stir its contents into one teaspoon (or less) of a suitable sweetened food product. This is usually suitable for children over 1 year.
To make a 75 mg dose, you need:
- One **MACSELTA 75 mg CAPSULES**
- Sharp scissors
- One small bowl
- Teaspoon (5 ml spoon)
- Water
- Sweet food to hide the bitter taste of the powder.
- Examples are: chocolate or cherry syrup, and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

Step 1: Check for the correct dose as indicated by your doctor.

Step 2: Pour all the powder into a bowl
Hold a **MACSELTA 75 mg CAPSULES** upright over a bowl and carefully snip off the rounded tip with scissors.
Pour **all** of the powder into the bowl.
Be careful with the powder, because it may irritate your skin and eyes.

Step 3: Sweeten the powder and give the dose
Add a small amount – no more than one teaspoonful – of sweet food to the powder in the bowl.
This is to hide the bitter taste of the **MACSELTA 75 mg CAPSULES** powder.
Stir the mixture well.
Give the whole contents of the bowl to the patient straight away.
If there is some mixture left in the bowl, rinse the bowl with a small amount of water and get the patient to drink it **all.**
Repeat this procedure every time you need to give the medicine.

Infants less than 1 year, and children weighing less than 40 kg
To make a smaller single dose, you need:
- One **MACSELTA 75 mg CAPSULES**
- Sharp scissors
- Two small bowls
- One 5 ml graduated syringe to measure out water
- Teaspoon (5 ml spoon)
- Water
- Sweet food to hide the bitter taste of the **MACSELTA 75 mg CAPSULES.**
- Examples are: chocolate or cherry syrup and dessert toppings such as caramel or fudge sauce.
  Or you can make sugar water: mix a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

Step 1: Pour all the powder into a bowl
Hold a **MACSELTA 75 mg CAPSULES** upright over one of the bowls and carefully snip off the rounded tip with scissors. Be careful with the powder: it may irritate your skin and eyes.
Pour **all** of the powder into the bowl, whatever the dose you are making.
The amount is the same whether you are treating or preventing flu.

Step 2: Add water to dilute the medicine
Use the graduated syringe to draw up 5 ml of water.
Add the water to the powder in the bowl.
Stir the mixture with the teaspoon for about 2 minutes.
Don't worry if not all of the powder dissolves. The undissolved powder is just inactive ingredients.

Step 3: Choose the correct amount for your child's weight as indicated by your doctor.

Step 4: Draw up the liquid mixture
Draw up the correct amount of liquid mixture from the first bowl.
Draw it up carefully so as not to include air bubbles.
Gently squirt the correct dose into the second bowl.

Step 5: Sweeten and give to the child
Add a small amount – no more than one teaspoonful – of a sweet food to the second bowl.
This is to hide the bitter taste of the **MACSELTA 75 mg CAPSULES.**
Mix the sweet food and **MACSELTA 75 mg CAPSULES** liquid **well.**
Give the whole contents of the second bowl (**MACSELTA 75 mg CAPSULES** liquid mixture with sweet food added) to the child straight away.
If there is anything left in the second bowl, rinse the bowl with a small amount of water and get the child to drink it all. For children unable to drink from a bowl, spoon-feed or use a bottle to feed the child the remaining liquid.
Give the child something to drink.
Throw away any unused liquid left in the first bowl.
Repeat this procedure every time you need to give the medicine.

If you take more MACSELTA 75 mg CAPSULES 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.
- Seek emergency medical attention if you think you have taken too much of **MACSELTA 75 mg CAPSULES.**

If you forget to take MACSELTA 75 mg CAPSULES
If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking MACSELTA 75 mg CAPSULES
If treatment with **MACSELTA 75 mg CAPSULES** is stopped earlier than your doctor has prescribed, the symptoms of flu may come back. Always complete the course that your doctor prescribed.

4. Possible side effects

MACSELTA 75 mg CAPSULES can have side effects.
Not all the side effects reported for **MACSELTA 75 mg CAPSULES** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MACSELTA 75 mg CAPSULES**, please consult your doctor, pharmacist or healthcare professional for advice.
If any of the following happens, stop taking MACSELTA 75 mg CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and breathing difficulties.
- Sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties breathing.
- Complicated, possibly life-threatening allergic reaction, severe inflammation of the outer and possibly inner skin, initially with fever, sore throat, and fatigue, skin rashes, leading to blisters, peeling, shedding of larger areas of skin, possible breathing difficulties and low blood pressure (Stevens-Johnson syndrome and toxic epidermal necrolysis).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MACSELTA 75 mg CAPSULES.** You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Convulsions and delirium, including altered level of consciousness
- Confusion, abnormal behaviour
- Delusions, hallucinations, agitation, anxiety, nightmares, self-injury
- Conjunctivitis (red eyes and discharge or pain in the eye)
- Liver disorders or liver failure with yellowing of the skin and white of the eyes, change in stool colour, changes in behaviour.
- Gastrointestinal bleeding: prolonged bleeding from the large bowel or spitting up blood.

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:
- Bronchitis, cold sores, upper respiratory tract infections (inflammation of the nose, throat and sinuses), middle ear infection, earache, cough, sore throat, runny nose, nasal congestion
- Headache, sleeping difficulties, dizziness (including vertigo)
- Nausea, vomiting, stomach ache, upset stomach, upper abdominal fullness
- Pain, pain in limb, tiredness, fever

Less frequent side effects:
- Thrombocytopenia (low platelet count)
- Swelling, or enlargement, of the lymph nodes
- Allergic reactions
- Altered level of consciousness
- Visual disturbances
- Tympanic membrane (eardrum) disorder.
- Heart rhythm abnormalities
- Asthma, bleeding nose
- Increased liver enzymes
- Skin reactions (Inflammation of the skin, red and itchy rash, scaling skin)

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 Drug Reaction Reporting Form**", 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 **MACSELTA 75 mg CAPSULES.**

5. How to store MACSELTA 75 mg CAPSULES

Store at or below 25 °C (room temperature). Protect from light and moisture.
Store all medicines out of reach of children.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / 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 MACSELTA 75 mg CAPSULES contains
The active substance is oseltamivir phosphate equivalent to oseltamivir 75 mg
The other ingredients include croscarmellose sodium, pregelatinised starch, povidone, sodium stearyl fumarate, talc, hard gelatin capsules containing gelatin, iron oxide red, iron oxide yellow, iron oxide black and titanium dioxide.

What MACSELTA 75 mg CAPSULES looks like and contents of the pack
Light yellow cap and grey body size '2' hard gelatin capsule containing white to off white granules with "75 mg" on cap and "M 55" on body imprinted with blue ink.

Blister Pack:
Blister pack with silver coloured 25 micron aluminium foil / 6-8 gsm HSL as lidding material and clear film PVC/PE/PVdC: 250/25/50 micron as forming material containing 10 or 28 capsules. The blister shall be placed in a carton with package leaflet.

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

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17 August 2021

Registration number
MACSELTA 75 mg CAPSULES: 52/20.2.8/0171

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://macleodssaproducts.co.za/ or contact 011 682 1169

MACSELTA 75 mg CAPSULES
PM03928402

Front Side

335 mm

260 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

MACSELTA 75 mg CAPSULES
Oseltamivirfosfaat 75 mg
Suikervry

Lees hierdie hele inligtingsblad aandagtig deur, voordat jy MACSELTA 75 mg CAPSULES begin gebruik
- Hou hierdie inligtingsblad. Dit mag wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of apteker.
- **MACSELTA 75 mg CAPSULES** is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander mense te deel nie. Selfs al het hulle dieselfde simptome as jy, kan dit vir hulle skadelik wees.

Wat is in hierdie inligtingsblad?
1. Wat **MACSELTA 75 mg CAPSULES** is en waarvoor dit gebruik word.
2. Wat jy behoort te weet voordat jy **MACSELTA 75 mg CAPSULES** neem.
3. Hoe om **MACSELTA 75 mg CAPSULES** te neem
4. Moontlike newe-effekte
5. Hoe om **MACSELTA 75 mg CAPSULES** te berg
6. Inhoud van die pak en ander inligting

1. Wat MACSELTA 75 mg CAPSULES is en waarvoor dit gebruik word

MACSELTA 75 mg CAPSULES word gebruik vir volwassenes, adolessente en kinders ouer as 1 jaar wie griepsimptome vir 2 dae of minder gehad het. **MACSELTA 75 mg CAPSULES** word ook gebruik om sommige soorte griep in volwassenes en kinders (ouer as 1 jaar oud) te voorkom, wanneer hulle tyd spandeer het met iemand wat die griep het of wanneer daar 'n griepuitbraak is.
PANDEMIESE GEBRUIK:
MACSELTA 75 mg CAPSULES is aangedui vir die behandeling van babas 6 – 12 maande oud slegs gedurende 'n pandemiese uitbraak van griep en nie vir endemiese (seisonale) griep gebruik nie.
MACSELTA 75 mg CAPSULES werk deur die verspreiding, van die griepvirus in die liggaam, te stop. **MACSELTA 75 mg CAPSULES** help om die tydperk wat griepsimptome, soos 'n verstopte- of loopneus, seerkeel, hoes, spier- of gewrigspyne, moegheid, hoofpyn, koors en koukoors aanhou, te verkort. **MACSELTA 75 mg CAPSULES sal** nie bakteriële infeksies, wat as 'n komplikasie van die griep kan voorkom, voorkom nie.

2. Wat jy behoort te weet voordat jy MACSELTA 75 mg CAPSULES neem of gee

Moet nie **MACSELTA 75 mg CAPSULES** neem of gee nie:
- indien jy allergies (*hipersensitief*) vir oseltamivir, of enige van die ander bestanddele van **MACSELTA 75 mg CAPSULES,** gelys in afdeling 6 is.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met **MACSELTA 75 mg CAPSULES:**
- Sommige mense wat **MACSELTA 75 mg CAPSULES** gebruik, het newe -effekte gehad van skielike verwarring, ylhoofdigheid, hallusinasies, ongewone gedrag. Hierdie simptome het meestal in kinders voorgekom. Enigiemand wat **MACSELTA 75 mg CAPSULES** gebruik, moet fyn dopgehou word vir tekens van verwarring of ongewone gedrag. Skakel onmiddellik jou dokter indien jy, of jou kind wat **MACSELTA 75 mg CAPSULES** gebruik, enige van hierdie simptome het.
- Vra jou dokter of jy elke jaar 'n griepinenting moet kry. **MACSELTA 75 mg CAPSULES** neem nie die plek van 'n jaarlikse griepvaksien in nie. Dit word aanbeveel dat 'n jaarlikse griepinspuiting geneem moet word, om te help om jou elke jaar te beskerm teen nuwe soorte van griepvirusse.
- Stel jou dokter in kennis indien jy probleme met jou niere het. As dit die geval is, mag dit nodig wees vir aanpassing van jou **MACSELTA 75 mg CAPSULES** dosis.

Ander medisyne en MACSELTA 75 mg CAPSULES
Vertel altyd jou gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).
Die volgende medisyne is veral belangrik:
- probenesied (gebruik om jig te behandel)

MACSELTA 75 mg CAPSULES met voedsel en drank:
MACSELTA 75 mg CAPSULES kan met of sonder voedsel geneem word. Neem van **MACSELTA 75 mg CAPSULES** saam met voedsel kan die moontlikheid om siek te voel of te word (naarheid en braking) verminder.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat jy **MACSELTA 75 mg CAPSULES** neem.
- Moet nie **MACSELTA 75 mg CAPSULES** neem indien jy swanger is nie. Stel jou dokter onmiddellik in kennis indien jy swanger is, of van plan is om swanger te raak.
- Moet nie borsvoed indien jy **MACSELTA 75 mg CAPSULES** neem nie.

Bestuur en gebruik van masjinerie
MACSELTA 75 mg CAPSULES kan newe-effekte soos duiseligheid en visuele steurnisse veroorsaak, indien dit voorkom, kan jou vermoë om te bestuur of masjiene te gebruik aangetas word.

3. Hoe om MACSELTA 75 mg CAPSULES te neem

Moet nie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Neem, of gee altyd **MACSELTA 75 mg CAPSULES** presies soos jou dokter jou opdrag gegee het. Jy behoort jou dokter of apteker te vra, indien jy onseker is.
Indien jy onder die indruk is dat die effek van **MACSELTA 75 mg CAPSULES** te sterk of te swak is, praat dan met jou dokter of apteker.
Die aanbevole dosis in volwassenes is:
Vir die behandeling van griep:
Behandeling behoort binne die eerste of tweede dag, na die aanvang van die simptome van influensa, te begin.
Volwassenes en adolessente ouer as 13 jaar: neem een **MACSELTA 75 mg CAPSULES** twee keer per dag vir 5 dae. Dit is gewoonlik gerieflik om een dosis in die oggend en een in die aand te neem. Dit is belangrik om die hele kursus van 5 dae te voltooi, selfs al begin jy vinnig beter voel.
Kinders ouer as 8 jaar of wat meer as 40 kg weeg wat instaat is om kapsules te kan sluk, moet een **MACSELTA 75 mg CAPSULES**, twee keer per dag gegee word.

Om griep te voorkom of na blootstelling aan 'n besmette persoon:
Behandeling moet binne twee dae na blootstelling begin.
Volwassenes en adolessente ouer as 13 jaar: neem een **MACSELTA 75 mg CAPSULES** een keer per dag vir 10 dae.
Kinders wat meer as 40 kg weeg en wat in staat is om kapsules te kan sluk, moet een keer per dag, vir 10 dae, een **MACSELTA 75 mg CAPSULES** gegee word.
Behandeling kan vir tot 6 weke duur, tydens 'n gemeenskapsuitbraak van influensa.

Mense wat dit moeilik vind om kapsules te neem: jy kan 'n vloeibare vorm van **MACSELTA 75 mg CAPSULES** van hierdie kapsules by die apteek, of tuis maak.
Die dosis is dieselfde vir behandeling of voorkoming van griep. Die verskil is hoe gereeld dit gegee word.
Maak vloeibare MACSELTA 75 mg CAPSULES tuis
Indien jy die korrekte kapsule sterkte het vir die dosis wat benodig word ('n 75 mg dosis), sal jy die kapsule oopmaak en die inhoud daarvan in een teelepel (of minder) van 'n geskikte versoete voedselproduk in roer. Dit is gewoonlik geskik vir kinders ouer as 1 jaar.
Om 'n 75 mg dosis te maak, benodig jy:
- Een **MACSELTA 75 mg CAPSULES**
- Skerp skêr
- Een klein bakkie
- Teelepel (5 ml lepel)
- Water
- Soet kos, om die bitter smaak van die poeier te verbloem.
- Voorbeelde is: sjokolade of kersiestroop, en nageregbedekkings soos karamel- of fudge - sous. Of, jy kan suikerwater maak: meng 'n teelepel water met 'n driekwart (3/4) teelepel suiker.

Stap 1: Maak seker van die korrekte dosis soos deur jou dokter aangedui.

Stap 2: Gooi al die poeier in die bakkie in
Hou 'n **MACSELTA 75 mg CAPSULES** regop oor 'n bakkie en sny die afgeronde punt versigtig af met 'n skêr.
Gooi al die poeier in die bakkie in.
Wees versigtig met die poeier, want dit kan moontlik jou vel en oë irriteer.

Stap 3: Versoet die poeier en gee die dosis
Voeg 'n klein hoeveelheid - nie meer as een teelepel vol nie – van soet kos by die poeier in die bakkie.
Hierdie is om die bitter smaak van die **MACSELTA 75 mg CAPSULES** poeier te verbloem.
Roer die mengsel **goed.**
Gee die totale inhoud van die bakkie onmiddellik aan die pasiënt.
Indien daar van die mengsel agterbly in die bakkie, spoel die bakkie uit met 'n klein hoeveelheid water, en laat die pasiënt dit alles drink.
Herhaal hierdie prosedure elke keer as jy die medisyne moet gee.

Babas jonger as 1 jaar, en kinders wat minder as 40 kg weeg
Om 'n kleiner enkele dosis te maak, benodig jy:
- Een **MACSELTA 75 mg CAPSULES** kapsule
- Skerp skêr
- Twee klein bakkies
- Een 5 ml gegradeerde spuit om water uit te meet
- Teelepel (5 ml lepel)
- Water
- Soet kos om die bitter smaak van die **MACSELTA 75 mg CAPSULES** te verbloem.
- Voorbeelde is: sjokolade of kersiestroop en nageregbedekkings soos karamel- of fudge - sous.
  Of jy kan suikerwater maak: meng 'n teelepel water met 'n driekwart (3/4) teelepel suiker.

Stap 1: Gooi al die poeier in die bakkie in
Hou 'n **MACSELTA 75 mg CAPSULES** regop oor een van die bakkies en sny die afgeronde punt versigtig af met 'n skêr. Wees versigtig met die poeier, want dit kan moontlik jou vel en oë irriteer.
Gooi al die poeier in die bakkie in, ongeag van die dosis wat jy maak.
Die hoeveelheid is dieselfde, of jy griep behandel, of voorkom.

Stap 2: Voeg water by om die medisyne te verdun
Gebruik die gegradeerde spuit om 5 ml water op te trek.
Voeg die water by die poeier in die bakkie.
Roer die mengsel met die teelepel vir ongeveer 2 minute.
Moet nie bekommerd wees indien al die poeier nie oplos nie. Die onopgeloste poeier is net onaktiewe bestanddele.

Stap 3: Kies die korrekte hoeveelheid vir jou kind se gewig soos aangedui deur jou dokter.

Stap 4: Trek die vloeistofmengsel op
Trek die korrekte hoeveelheid van vloeistofmengsel uit die eerste bakkie op.
Trek dit versigtig op om nie lugborrels in te sluit nie.
Spuit versigtig die korrekte dosis in die tweede bakkie in.

Stap 5: Versoet en gee aan die kind
Voeg 'n klein hoeveelheid – nie meer as een teelepel vol nie – van 'n soet kos by die tweede bakkie.
Dit is om die bitter smaak van die **MACSELTA 75 mg CAPSULES** te verbloem.
Meng die soet kos en **MACSELTA 75 mg CAPSULES** vloeistof goed.
Gee die hele inhoud van die tweede bakkie **(MACSELTA 75 mg CAPSULES** vloeistofmengsel met soet kos bygevoeg) onmiddellik aan die kind.
Indien daar enige iets in die tweede bakkie agterbly, spoel die bakkie met 'n klein hoeveelheid water en laat die kind dit alles drink. Vir kinders wat nie uit 'n bakkie kan drink nie, voer met 'n lepel of gebruik 'n bottel om die oorblywende vloeistof aan die kind te voer.
Gee die kind iets om te drink.
Gooi enige ongebruikte vloeistof wat in die eerste bakkie oorbly, weg.
Herhaal hierdie prosedure elke keer as jy die medisyne moet gee.

Indien jy meer MACSELTA 75 mg CAPSULES neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
- Soek nood mediese hulp indien jy dink dat jy te veel **MACSELTA 75 mg CAPSULES** geneem het.

Indien jy vergeet om MACSELTA 75 mg CAPSULES te neem
Indien jy vergeet om 'n dosis te neem, neem dit sodra jy daarvan onthou, en gaan dan aan soos voorheen. Moet nie 'n dubbele dosis neem om vir die vergete individuele dosisse op te maak nie.

Indien jy ophou om MACSELTA 75 mg CAPSULES te neem
Indien behandeling met **MACSELTA 75 mg CAPSULES** vroeër gestaak word as wat jou dokter voorgeskryf het, kan die simptome van griep terugkom. Voltooi altyd die kursus wat jou dokter voorgeskryf het.

4. Moontlike newe-effekte

MACSELTA 75 mg CAPSULES kan newe-effekte hê.
Nie alle newe-effekte wat vir **MACSELTA 75 mg CAPSULES** aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid versleg of indien jy enige ongunstige effekte ervaar terwyl **MACSELTA 75 mg CAPSULES** geneem word, kontak asseblief jou dokter, apteker of gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om MACSELTA 75 mg CAPSULES te neem, en vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Erge allergiese reaksies, met swelling van gesig en vel, jeukende uitslag, lae bloeddruk en asemhalingsprobleme.
- Skielike aanvang van erge swelling van die vel, hoofsaaklik rondom die kop en nek area, insluitend oë en tong, met asemhalingsprobleme.
- Gekompliseerde, moontlik lewensgevaarlike allergiese reaksie, erge ontsteking van die buitenste en moontlik binneste vel, aanvanklik met koors, seerkeel, en moegheid, veluitslae wat tot blase lei, afskilfering, velafskeiding van groter ares van vel, moontlike asemhalingsprobleme en lae bloeddruk (Stevens-Johnson-sindroom en toksiese epidermale nekrolise).

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige reaksie op **MACSELTA 75 mg CAPSULES** gehad. Jy benodig dringende mediese aandag of hospitalisasie.

Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling by jou naaste hospitaal, indien jy enige van die volgende opmerk:
- Konvulsies en ylhoofdigheid, insluitend veranderde vlakke van bewussyn
- Verwarring, abnormale gedrag
- Waanvoorstellings, hallusinasies, rusteloosheid, angstigheid, nagmerries, selfbesering
- Konjunktivitis (rooi oë en afskeiding of pyn in die oë)
- Lewer afwykings of lewerversaking met vergeling van die vel en wit van die oë, verandering in kleur van stoelgang, verandering in gedrag.
- Gastrointestinale bloeding: langdurige bloeding uit die groot derm of spoeg bloed op.

Hierdie is almal ernstige newe-effekte. Jy kan moontlik dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Algemene newe-effekte:
- Brongitis, koorsblare, boonste lugweg infeksies (ontsteking van die neus, kael en sinusse), middeloor ontsteking, oorpyn, hoes, seerkeel, loopneus, neusverstopping
- Hoofpyn, slaapprobleme, duiseligheid (insluitend vertigo)
- Naarheid, braking, maagpyn, omgekrapte maag, boonste abdominale volheid
- Pyn, pyn in ledemaat, moegheid, koors

Minder algemene newe-effekte:
- Trombositopenie (lae bloedplaatjietelling)
- Swelling of vergroting van die limfkliere
- Allergiese reaksies
- Veranderde vlak van bewussyn
- Visuele steurnisse
- Timpaniese membraan (oordrom) versteuring.
- Hartritme abnormaliteite
- Asthma, neusbloeding
- Verhoogde lowerensieme
- Velreaksies (ontsteking van die vel, rooi en jeukende uitslag, afskilferende vel)

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, moet jy asseblief jou dokter of apteker daarvan in kennis stel.

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 inligtingsblad gelys is nie. Jy kan ook newe-effekte aanmeld by SAHPRA via die "**5.04 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 oor die veiligheid van **MACSELTA 75 mg CAPSULES** te verskaf.

5. Hoe om MACSELTA 75 mg CAPSULES te bewaar

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig en vog.
Bewaar alle medisyne buite bereik van kinders.
Bewaar in die oorspronklike verpakking / houer.
Hou die stulpstrook in die karton, totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer berg nie.
Moet nie na die vervaldatum wat aangebring is op die stulpstrook / etiket / karton / bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in die riool of rioolstelsel (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat MACSELTA 75 mg CAPSULES bevat
Die aktiewe bestanddeel is oseltamivirfosfaat ekwivalent aan 75 mg oseltamivir.
Die ander bestanddele sluit in: natriumkroskarmellose, voorafgelatiniseerde stysel, povidoon, natriumstearielfumaraat, talk, harde gelatienkapsules wat gelatien, rooi ysteroksied, geel ysteroksied, swart ysteroksied en titaniumdioksied bevat.

Hoe MACSELTA 75 mg CAPSULES lyk en die inhoud van die pak
Grootte '2' harde gelatienkapsule met liggeel dop en grys liggaam, bevat wit tot af-wit granules, met '75 mg' op die dop en 'M 55' op die liggaam met blou ink inbedruk.

Stulpverpakking:
Stulpverpakking wat 10 of 28 kapsules bevat, met silwer gekleurde 25 mikron aluminiumfoelie / 6-8 gsm HSL as dekmateriaal en deursigtige film PVC/PE/PVdC: 250/25/60 mikron as vormingsmateriaal. Die stulpstrook sal in 'n karton met inligtingsblad geplaas word.

Houer van die Sertifikaat van Registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Rylaan 1, Bassonia Rock, Uitbreiding 12,
Alberton, Suid Afrika

Hierdie inligtingsblad is laas hersien in:
17 Augustus 2021

Registrasienommer:
MACSELTA 75 mg CAPSULES: 52/20.2.8/0171

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

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MACLEODS

Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Professional information removed & dimension change

1. Product: MACSELTA 75 mg CAPSULES (Oseltamivir Capsules 75 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: 335 (L) x 260 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM03928402
11. Artwork has been made: Actual Size	12. Pharma code No.: 32964 mini
13. Barcode/NDC No: NA	14. Supersedes Item code No: PM03928401
15. Revision no: 01	16. A/W File name: X:\Oseltamivir\SA Private Market\01\Oseltamivir 75 mg PI & PIL- PM03928402.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
24/10/2023	Vanita Rajool	24/10/23	26/05/23	24/10/23	29/05/23

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.

QA 29/05/23

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03928401	01/09/22	27/10/22
2) Professional information removed & dimension change	PM03928402		

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