290 mm

DAPIFLO
5 / 10 mg
PM04287401

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DAPIFLO 5 mg
DAPIFLO 10 mg
Dapagliflozin

DO NOT USE DAPIFLO IF YOU HAVE TYPE 1 DIABETES.
There have been reports of metabolic acidosis, including ketoacidosis, in patients taking DAPIFLO.

Metabolic acidosis is an imbalance of acids in your blood, shown on blood tests. It is a serious and sometimes fatal condition that requires hospitalization. Risk factors for metabolic acidosis include sudden decrease of your insulin dose, prolonged fasting from food and drink, or increasing your insulin dose due to major surgery or serious illness, or alcohol abuse. Caution is advised when using DAPIFLO if you have these conditions.

Diabetic ketoacidosis is a type of metabolic acidosis. Diabetic ketoacidosis is an increase of ketone bodies in your blood or urine, shown on blood or urine tests. Risk factors for diabetic ketoacidosis include pancreatic conditions, such as inflammation of the pancreas or previous pancreatic surgery. Do not use DAPIFLO if you have these conditions.

Metabolic acidosis, including diabetic ketoacidosis, may occur in patients with Type 2 diabetes mellitus with normal (blood glucose test result below 11 mmol/L) or high blood sugar levels who are treated with DAPIFLO.

Contact a doctor or the nearest hospital straight away if you have the following symptoms even if your blood sugar levels are normal: nausea, vomiting, abdominal pain, fatigue, thirst, passing of large amounts of urine, shortness of breath and confusion. These symptoms could be a sign of metabolic or diabetic ketoacidosis.

DAPIFLO 5 mg contains 25 mg lactose monohydrate per tablet.
DAPIFLO 10 mg contains 50 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking DAPIFLO
- 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.
- **DAPIFLO** 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 **DAPIFLO** is and what it is used for
2. What you need to know before you take **DAPIFLO**
3. How to take **DAPIFLO**
4. Possible side effects
5. How to store **DAPIFLO**
6. Contents of the pack and other information

1. What DAPIFLO is and what it is used for

DAPIFLO contains dapagliflozin.

It belongs to a group of medicines called "sodium glucose co-transporter-2 (SGLT2) inhibitors". They work by blocking the SGLT2 protein in your kidney. By blocking this protein, blood sugar (glucose), salt (sodium) and water are removed from your body via the urine.

are used to treat the following conditions:
DAPIFLO is used in adult patients (aged 18 years and older) to treat:
Type 2 diabetes
- if your type 2 diabetes cannot be controlled with diet and exercise.
- **DAPIFLO** can be used on its own or together with other medicines to treat diabetes.

2. What you need to know before you take DAPIFLO

Do not take DAPIFLO:
- If you are allergic to dapagliflozin or any of the other ingredients of this medicine listed in section 6.
- If you are pregnant plan to become pregnant. Talk with your doctor about the best way to control your blood sugar while you are pregnant.
- If you are breastfeeding. Talk to your doctor if you would like to breastfeed your baby.
- If you have diabetes mellitus type 1 – the type that usually starts when you are young, and your body does not produce any insulin.
- If you have moderate or severe kidney disease or you are on dialysis.

Warnings and precautions

Take special care with **DAPIFLO:**
- If you are going to have a surgery.
- If you are eating less due to illness or surgery, or you are dieting
- If you have or have had problems with your pancreas.
- If you drink large amounts of alcohol, either every day or only from time to time.
- If you develop any of the following symptoms, which may be signs of ketoacidosis: nausea, vomiting, stomach-area (abdominal) pain, tiredness, difficulty breathing, increased levels of "ketone bodies" in your blood or urine. If this happens to you contact a doctor or the nearest hospital immediately.
- If you have mild kidney disease your doctor will want to monitor your kidney function on an ongoing basis.
- If you often get infections of the urinary tract.
- If you are allergic to any other medicine used to lower the amount of sugar in your blood.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking **DAPIFLO.**

Use in children and adolescents
The use of **DAPIFLO** in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and DAPIFLO
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tell your doctor or pharmacist if you are taking any of the following medicines:
- if you are taking a medicine used to remove water from the body (diuretic).
- if you have type 2 diabetes and are taking other medicines that lower the amount of sugar in your blood such as insulin or a "sulphonylurea" medicine. Your doctor may want to lower the dose of these other medicines, to prevent you from getting low blood sugar levels (hypoglycaemia).

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 **DAPIFLO**.

Do not take **DAPIFLO** if you are pregnant or are breastfeeding.

Driving and using machines
DAPIFLO has no or negligible influence on the ability to drive and use machines.
Taking this medicine with other medicines called sulphonylureas or with insulin can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines.

Do not drive or use any tools or machines, if you feel dizzy taking **DAPIFLO**

DAPIFLO contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take DAPIFLO

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

Always take **DAPIFLO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is one 10 mg tablet each day.

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

If you take more DAPIFLO 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.

If you forget to take DAPIFLO
It is important to take your **DAPIFLO** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking DAPIFLO
If **DAPIFLO** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **DAPIFLO** for as long as your doctor has prescribed.

4. Possible side effects

Diabetic ketoacidosis (diabetic coma) and similar side effects may occur. Symptoms are nausea, vomiting, abdominal pain, fatigue, thirst, passing of large volumes of urine, shortness of breath and mental confusion. Urgent medical attention is required.

DAPIFLO can have side effects.

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

If you have a hypersensitive (allergic) reaction, stop taking DAPIFLO and tell your doctor immediately or go to the casualty department of your nearest hospital.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Very dry or sticky mouth, feeling very thirsty
- Feeling very sleepy or tired
- Passing little or no water (urine)
- Fast heart beat

These are signs of losing too much fluid from your body (volume depletion or dehydration.)
- Fever or chills
- Burning sensation when passing water (urinating)
- Pain in your back or side
- Blood in your urine, although uncommon

These are signs of a severe infection of the urinary tract.
These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent
- Low blood sugar levels (hypoglycaemia) – when taking this medicine with other medication or insulin to treat your diabetes.

These are signs of low blood sugar (hypoglycaemia):
- shaking, sweating, feeling very anxious, fast heartbeat
- feeling hungry, headache, change in vision
- a change in your mood or feeling confused

Your doctor will tell you how to treat low blood sugar and what to do if you get any of the signs above.
- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)
- back pain
- passing more water (urine) than usual or needing to pass water more often
- High sugar levels (glucose) in urine (shown in tests).
- changes in the amount of cholesterol or fats in your blood (shown in tests)
- Broken bones, if you already have moderate kidney problems.
- increases in the amount of red blood cells in your blood (shown in tests)
- decreases in creatinine renal clearance (shown in tests) in the beginning of treatment
- Dizziness
- rash

Less frequent:
- loss of too much fluid from your body (dehydration, signs may include very dry or sticky mouth, passing little or no urine or fast heartbeat)
- Increased thirst
- Constipation
- Itching of the genitals
- Increased sweating
- Tight foreskin which may cause difficulty urinating or inflammation of glans or foreskin (phimosis).
- Awakening from sleep at night to pass urine
- Dry mouth
- Weight decreased
- Increases in creatinine (shown in laboratory blood tests) in the beginning of treatment.
- Increases in urea (shown in laboratory tests)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
Should your general health worsen or if you experience any untoward effects while taking **DAPIFLO**, please consult your healthcare provider for advice.

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 **DAPIFLO.**

5. How to store DAPIFLO

Store at or below 25 °C.
KEEP OUT OF THE 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 DAPIFLO contains
The active ingredient is dapagliflozin.
Contains sugar - lactose monohydrate
The other ingredients are:
Microcrystalline cellulose
Lactose monohydrate
Crospovidone
Sodium lauryl sulphate
Methylene chloride
Colloidal silicon dioxide
Magnesium stearate
Instamoldshield Aqua II Yellow

What DAPIFLO looks like and contents of the pack
DAPIFLO 5 mg: Each film-coated tablet contains 5 mg of dapagliflozin.
DAPIFLO 10 mg: Each film-coated tablet contains 10 mg of dapagliflozin.

Contents of the pack:
Tablets are packed in plain 25 micron aluminium foil and 25 micron OPA/ 45 micron aluminium foil/ 60 micron PVC on the other side. Pack sizes include 10's, 14's; 28's; 30's; 90's and 98's tablets.
Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Ground Floor, Block 1,
Bassonia Estate Office Park (east),
1 Cussonia Drive,
Bassonia Rock Ext 12
Alberton
Gauteng

This leaflet was last revised in
05 December 2023

Registration numbers
DAPIFLO 5 mg: 56/21.2/0682.680
DAPIFLO 10 mg: 56/21.2/0683.681

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

335 mm

290 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

DAPIFLO 5 mg
DAPIFLO 10 mg
Dapagliflosien

MOET NIE DAPIFLO GEBRUIK INDIEN JY TIPE 1-DIABETES HET NIE.

Daar is berigte van metaboliese asidose, insluitend ketoasidose, in pasiënte wat DAPIFLO neem.

Metaboliese asidose is 'n wanbalans van sure in jou bloed, wat in bloedtoetse getoon word. Dit is 'n ernstige en soms noodlottige toestand wat hospitalisering vereis. Risikofaktore vir metaboliese asidose sluit in skielike afname van jou insuliendosis, langdurige vas van voedsel en drank, of die verhoging van jou insuliendosis as gevolg van groot chirurgie of ernstige siekte, of alkoholmisbruik. Spesiale sorg moet geneem word wanneer jy DAPIFLO gebruik indien jy hierdie toestande het.

Diabetiese ketoasidose is 'n tipe metaboliese asidose. Diabetiese ketoasidose is 'n toename in ketoonliggame in jou bloed of uriene, wat in bloed- of urientoetse getoon word. Risikofaktore vir diabetiese ketoasidose sluit in pankreas toestande, soos ontsteking van die pankreas of vorige pankreaschirurgie. Moet nie DAPIFLO gebruik indien jy hierdie toestande het nie.

Metaboliese asidose, insluitend diabetiese ketoasidose, kan voorkom in pasiënte met Tipe 2-diabetes mellitus met normale (bloedglukosetoetsresultaat onder 11 mmol/L) of hoë bloedsuikervlakke wat met DAPIFLO behandel word.

Kontak onmiddellik 'n dokter of die naaste hospitaal indien jy die volgende simptome het, selfs al is jou bloedsuikervlakke normaal: naarheid, braking, abdominale pyn, moegheid, dors, passeer van groot hoeveelhede uriene, kort van asem en verwarring. Hierdie simptome kan 'n teken wees van metaboliese- of diabetiese ketoasidose.

DAPIFLO 5 mg bevat 25 mg laktosemonohidraat per tablette.
DAPIFLO 10 mg bevat 50 mg laktosemonohidraat per tablette.

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy DAPIFLO begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer
- **DAPIFLO** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

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

1. Wat DAPIFLO is en waarvoor dit gebruik word

DAPIFLO bevat dapagliflosien.

Dit behoort aan 'n groep van medisyne genaamd "natriumglukose mede-vervoerder-2 (SGLT2) inhibeerders". Hulle werk deur die SGLT2-proteïen in jou nier te blokkeer. Deur hierdie proteïen te blokkeer, word bloedsuiker (glukose), sout (natrium) en water deur middel van die uriene uit jou liggaam verwyder.

word gebruik om die volgende toestande te behandel:
DAPIFLO word in volwasse pasiënte (ouderdom 18 jaar en ouer) gebruik om te behandel:
- Tipe 2-diabetes
  - indien jou tipe 2-diabetes nie met dieet en oefening beheer kan word nie.
  - **DAPIFLO** kan op sy eie of saam met ander medisyne gebruik word om diabetes te behandel.

2. Wat jy behoort te weet voordat jy DAPIFLO neem

Moet nie DAPIFLO neem nie:
- Indien jy allergies is vir dapagliflosien of enige van die ander bestanddele van hierdie medisyne wat in afdeling 6 gelys word.
- Indien jy swanger is, beplan om swanger te raak. Praat met jou dokter oor die beste manier om jou bloedsuiker te beheer terwyl jy swanger is.
- Indien jy borsvoed. Praat met jou dokter indien jy jou baba wil borsvoed.
- Indien jy diabetes mellitus tipe 1 het – die tipe wat gewoonlik begin wanneer jy jonk is, en jou liggaam geen insulien produseer nie.
- Indien jy matige of ernstige niersiekte het of jy op dialise is.

Waarskuwings en voorsorgmaatreëls
Spesiale sorg moet geneem word met **DAPIFLO:**
- Indien jy 'n operasie gaan ondergaan.
- Indien jy minder eet as gevolg van siekte of chirurgie, of jy dieet
- Indien jy probleme met jou pankreas het of gehad het.
- Indien jy groot hoeveelhede alkohol drink, hetsy elke dag of net van tyd tot tyd.
- Indien jy enige van die volgende simptome ontwikkel, wat tekens van ketoasidose kan wees: naarheid, braking, maagarea (abdominale) pyn, moegheid, probleme met asemhaling, verhoogde vlakke van "ketoonliggame" in jou bloed of uriene. Indien dit met jou gebeur, kontak onmiddellik 'n dokter of die naaste hospitaal.
- Indien jy ligte niersiekte het, sal jou dokter jou nierfunksie deurlopend wil monitor.
- Indien jy dikwels infeksies in die urienweg ky.
- Indien jy allergies is vir enige ander medisyne wat gebruik word om die hoeveelheid suiker in jou bloed te verlaag

Indien enige van die bogenoemde op jou van toepassing is (of jy onseker is), praat met jou dokter of apteker voordat jy **DAPIFLO** neem.

Gebruik in kinders en adolessente
Die gebruik van **DAPIFLO** in kinders en adolessente (onder die ouderdom van 18 jaar) word nie aanbeveel nie.

Ander medisyne en DAPIFLO
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker indien jy enige van die volgende medisyne gebruik:
- indien jy 'n medisyne neem wat gebruik word om water uit die liggaam te verwyder (diuretika).
- indien jy tipe 2-diabetes het en ander medisyne gebruik wat die hoeveelheid suiker in jou bloed verlaag, soos insulien of 'n "sulfonielureum"-middel. Jou dokter sal moontlik die dosis van hierdie ander medisyne wil verlaag om te verhoed dat jy lae bloedsuikervlakke (hipoglukemie) kry.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **DAPIFLO** neem

Moet nie **DAPIFLO** neem indien jy swanger is of borsvoed nie.

Bestuur en gebruik van masjinerie
DAPIFLO het geen of onbeduidende invloed op die vermoë om te bestuur en masjiene te gebruik.
Indien jy hierdie medisyne saam met ander medisyne naamlik sulfonieluureums of insulien gebruik, kan dit te lae bloedsuikervlakke (hipoglukemie) veroorsaak, wat simptome soos bewing, sweet en verandering in visie kan veroorsaak, en kan jou vermoë om te bestuur en masjiene te gebruik, affekteer.
Moet nie bestuur of enige gereedskap of masjiene gebruik indien jy duiselig voel wanneer jy **DAPIFLO** neem nie.

DAPIFLO bevat laktose
Indien jy deur jou dokter meegedeel is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy hierdie medisyne neem.

3. Hoe om DAPIFLO te neem

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

Neem altyd **DAPIFLO** presies soos jou dokter jou opdrag gegee het. Jy moet met jou dokter of apteker bevestig indien jy nie seker is nie.

Die aanbevole dosis is een 10 mg tablette elke dag.

Indien jy die indruk het dat die effek van **DAPIFLO** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer DAPIFLO 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 giftbeheersentrum.

Indien jy vergeet om DAPIFLO te neem
Dit is belangrik om jou **DAPIFLO** gereeld op dieselfde tyd elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit sodra jy onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse gelyktydig neem om vir 'n oorgeslane dosis op te maak nie.

Indien jy ophou om DAPIFLO te neem
Indien **DAPIFLO** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **DAPIFLO** vir solank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

Diabetiese ketoasidose (diabetiese koma) en soortgelyke newe-effekte kan voorkom.
Simptome is naarheid, braking, abdominale pyn, moegheid, dors, passering van groot volumes uriene, kort van asem en geestelike verwarring. Dringende mediese aandag word benodig.
DAPIFLO kan newe-effekte hê.
Nie al die newe-effkte wat vir **DAPIFLO** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongewenste effekte ervaar terwyl jy **DAPIFLO** neem, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien jy 'n hipersensitiewe (allergiese) reaksie het, hou op om DAPIFLO te neem en vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal.
Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- Baie droë of klewerige mond, voel baie dors
- Voel baie slaperig of moeg
- Passeer min of geen water (uriene)
- Vinnige hartklop

Hierdie is tekens dat jy te veel vloeistof uit jou liggaam verloor (volume verlies of dehidrasie.)
- Koors of koukoors
- Brandende sensasie wanneer water passeer (urineer)
- Pyn in jou rug of sy
- Bloed in jou uriene, alhoewel ongewoon

Hierdie is tekens van 'n ernstige infeksie in die urienweg.
Hierdie is almal baie ernstige newe-effekte. Jy mag dringende mediese aandag nodig hê.

Sê vir jou dokter indien jy enige van die volgende waarneem:
Algemeen
- Lae bloedsuikervlakke (hipoglukemie) – wanneer jy hierdie medisyne saam met ander medikasie of insulien gebruik om jou diabetes te behandel

Hierdie is tekens van lae bloedsuiker (hipoglukemie):
- bewe, sweet, voel baie angstig, vinnige hartklop
- honger voel, hoofpyn, verandering in visie
- 'n verandering in jou bui of verward voel

Jou dokter sal aan jou verduidelik hoe om lae bloedsuiker te behandel en wat om te doen indien jy enige van die bogenoemde tekens kry.
- genitale infeksie (sproei) van jou penis of vagina (tekens kan irritasie, gejeuk, ongewone afskeiding of reuk insluit)
- rugpyn
- meer water as gewoonlik passeer (uriene) of meer gereeld moet water passeer
- Hoë suikervlakke (glukose) in uriene (getoon in toetse).
- veranderinge in die hoeveelheid van cholesterol of vette in jou bloed (getoon in toetse)
- Gebreekte bene, indien jy reeds matige nierprobleme het.
- toenames in die hoeveelheid van rooibloedselle in jou bloed (getoon in toetse)
- afname in renale kreatinien opruiming (getoon in toetse) aan die begin van behandeling
- Duiseligheid
- Uitslag

Minder algemeen
- verlies van te veel vloeistof uit jou liggaam (dehidrasie, tekens kan baie droë of klewerige mond insluit, passering van min of geen uriene of vinnige hartklop)
- Toename in dors
- Hardlywigheid
- Geslagsdele wat jeuk
- Verhoogde sweet
- Vernoude voorhuid wat probleme met urinering of ontsteking van glans of voorhuid kan veroorsaak (voorhuidklemming).
- Snags wakker word om uriene te passer
- Droë mond
- Verliess van gewig
- Toenames in kreatinien (getoon in laboratorium bloedtoetse) aan die begin van behandeling.
- Toenames in ureum (getoon in laboratoriumtoetse)

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.
Sou jou algemene gesondheid versleg of indien jy enige ongewenste effekte ervaar terwyl jy **DAPIFLO** neem, raadpleeg asseblief jou gesondheidsorgverskafer vir advies.

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 gelys is 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 beskikbaar te stel aangaande die veiligheid van **DAPIFLO.**

5. Hoe om DAPIFLO te bewaar

Bewaar by of benede 25°C.
BEWAAR BUITE DIE BEREIK VAN KINDERS.
Stoor in die oorspronklike verpakking/houer.
Hou die stulpe in die buitenste karton totdat dit benodig word vir gebruik.
Moet nie in die badkamer bêre nie
Moet nie gebruik na die vervaldatum wat aangebring is op die stulpe/etiket/karton /bottel nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat DAPIFLO bevat
Die aktiewe bestanddeel is dapagliflosien.
Bevat suiker - laktosemonohidraat
Die ander bestanddele is:
Mikrokristallyne sellulose
Laktosemonohidraat
Krospovidoon
Natriumlaurielsulfaat
Metileenchloried
Kolloidale silikondioksied
Magnesiumstearaat
Insta klamskild Aqua II Geel

Hoe DAPIFLO lyk en inhoud van die pak
DAPIFLO 5 mg: Elke filmbedekte tablet bevat 5 mg dapagliflosien.
DAPIFLO 10 mg: Elke filmbedekte tablet bevat 10 mg dapagliflosien.

Inhoud van die pak
Tablette is verpak in gewone 25 mikron aluminiumfoelie en 25 mikron OPA/ 45 mikron aluminiumfoelie/ 60 mikron PVC aan die ander kant. Pakgroottes sluit 10's, 14's; 28's; 30's; 90's en 98's tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1,
Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1,
Bassonia Rock, Uitbr. 12,
Alberton
Gauteng

Hierdie inligtingstuk was hersien in
05 Desember 2023

Registrasienommer
DAPIFLO 5 mg: 56/21.2/0682.680
DAPIFLO 10 mg: 56/21.2/0683.681

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

335 mm

MASTER COPY

MACLEODS

Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: DAPIFLO 5/10 mg (Dapagliflozin 5/10 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: 335(L) X 290(W) mm
9. Design / Style: Booklet type	10. Item code No.: PM04287401
11. Artwork has been made: Actual Size	12. Pharma code No.: 33498 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. A/W File name: Z:\DAPAGLIFLOZIN TABLETS\01\DAPAGLIFLOZIN TABLETS 5-10 MG PIL - PM04287401.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
30/01/24	Vanita Rajool	30/01/24	03/02/24	06/02/24	10/02/24

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	PM04287401		

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