Front Side

350 mm

EMPAMAK 10/25
(film-coated tablet)
PM04340735

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

EMPAMAK 10 (film coated tablet)
Contains empagliflozin 10 mg
Contains Sugar (42,4 mg of lactose monohydrate)
EMPAMAK 25 (film coated tablet)
Contains empagliflozin 25 mg
Contains Sugar (106,0 mg of lactose monohydrate)

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

Do not take EMPAMAK if you have 'type 1' diabetes.
EMPAMAK is not used to control body weight.
There have been reports of 'metabolic acidosis' or 'ketoacidosis' in people with diabetes mellitus taking EMPAMAK, which is life threatening and needs to be treated in hospital. Cases of ketoacidosis have also been reported in people without diabetes mellitus.
If you have any symptoms of metabolic acidosis such as feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, you must immediately contact a doctor or the nearest hospital in order to be assessed for metabolic acidosis, even if your blood glucose level is below 11 mmol/L.
Please refer also to Warnings and precautions.

1. What EMPAMAK is and what it is used for

EMPAMAK contains empagliflozin.
EMPAMAK is used to treat 'type 2 diabetes' in adults (aged 18 years and older) to improve blood sugar (glucose) control together with diet and exercise. **EMPAMAK** must not be used to control your blood sugar if you have moderate or severe kidney problems.
EMPAMAK is a medicine which is taken by mouth to treat high blood sugar levels. The active ingredient in **EMPAMAK**, empagliflozin, works by blocking a protein in the kidneys called sodium glucose cotransporter 2 (SGLT2).

EMPAMAK is not to be used in people with 'type 1 diabetes'.
EMPAMAK can be used alone or can also be taken with other medicines used to lower your blood sugar. These may be medicines taken by mouth or insulin given by injection.

Because of how **EMPAMAK** works, your urine will test positive for sugar while you are taking **EMPAMAK**. Your blood sugar control cannot therefore be assessed by using the presence of sugar (glucose) in your urine to monitor your blood sugar.

It is important to follow the advice about diet and exercise that you have been given by your healthcare professional.

2. What you need to know before you take EMPAMAK

Do not take EMPAMAK:
- if you are allergic to empagliflozin or any of the other ingredients of this medicine (listed in **section 6**)
- If you have type 1 diabetes
- If you have increased levels of ketone bodies in your urine or blood.
- If you have severe kidney problems or have kidney failure and are on renal dialysis.
- If you are pregnant or if you are breastfeeding your baby.

Warnings and precautions
Take special care with **EMPAMAK**
- Ketoacidosis: If you experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, contact a doctor or the nearest hospital straight away. These symptoms could be a sign of “ketoacidosis” – a rare, but serious, sometimes life-threatening problem you can get with diabetes because of increased levels of “ketone bodies” in your urine or blood, seen in tests. The risk of developing ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.
- If you have “type 1 diabetes”. This type usually starts when you are young and your body does not produce any insulin. You should not take **EMPAMAK** to treat your type 1 diabetes.
- If you have serious kidney or liver problems – your doctor may ask you to take a different medicine.
- There might be at risk of dehydration, for example:
  - If you are being sick, have diarrhoea or fever, or if you are not able to eat or drink
  - If you are taking medicines that increase urine production [diuretics] or lower blood pressure
  - If you are over 75 years old. Possible signs are listed in **section 4** under 'dehydration'. Your doctor may ask you to stop taking **EMPAMAK** until you recover to prevent loss of too much body fluid. Ask about ways to prevent dehydration.
- If you are 85 years old or older as you should not start taking **EMPAMAK** due to limited therapeutic experience
- If you have a serious infection of the kidney or the urinary tract with fever. Your doctor may ask you to stop taking **EMPAMAK** until you have recovered.
- Talk to your doctor immediately if you develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier's gangrene which destroys the tissue under the skin. Fournier's gangrene has to be treated immediately.
- Foot care: Like for all diabetic patients it is important to check your feet regularly and adhere to any other advice regarding foot care given by your health care professional.
- Kidney function: Your kidneys should be checked before you start taking and whilst you are on this medicine.
- Urine glucose: Because of how this medicine works, your urine will test positive for sugar while you are taking this medicine.

Children and adolescents
EMPAMAK is not recommended for children and adolescents under 18 years, because it has not been studied in these patients.

Other medicines and EMPAMAK
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 medicines that increase urine production (diuretics). Your doctor may ask you to stop taking **EMPAMAK**. Possible signs of losing too much fluid from your body are listed in **section 4**.
- If you 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 your blood sugar levels from getting too low (hypoglycaemia).

EMPAMAK with food and drink and alcohol:
- You can take **EMPAMAK** 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. Do not use **EMPAMAK** if you are pregnant. It is unknown if **EMPAMAK** is harmful to the unborn child. Do not use **EMPAMAK** if you are breast-feeding. It is not known if **EMPAMAK** passes into human breast milk.

Driving and using machines
EMPAMAK has minor influence on the ability to drive and use machines. Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause blood sugar levels to drop too low (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 while taking **EMPAMAK**.
It is not always possible to predict to what extent **EMPAMAK** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **EMPAMAK** affects them.

EMPAMAK contains lactose
Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **EMPAMAK**

3. How to take EMPAMAK

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

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

The recommended starting dosage of **EMPAMAK** is one 10 mg tablet once a day. Your doctor may tell you to increase the dose to 25 mg once a day if your blood glucose is not adequately controlled with a dose of 10 mg per day.
Your doctor will prescribe the strength that is right for you. Do not change your dose unless your doctor has told you to.

Method of administration
Swallow the tablet whole with water. You can take the tablet with or without food. You can take the tablet at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.

Continue to take **EMPAMAK** as long as your doctor prescribes it so you can continue to help control your blood sugar. Your doctor may prescribe **EMPAMAK** together with other diabetes medicines. Remember to take all medicines as directed by your doctor to achieve the best results for your health.

Diet and exercise can help our body use its blood sugar better. It is important to stay on the diet and exercise program recommended by your healthcare professional while taking **EMPAMAK**.
Check your blood sugar as your healthcare professional tells you to.
If you have the impression that the effect of **EMPAMAK** is too strong or too weak, talk to your doctor or pharmacist.
If you take more EMPAMAK 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 EMPAMAK
It is important to take your **EMPAMAK** 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 a double dose to make up for a forgotten dose. Never take two doses on the same day.

If you stop taking EMPAMAK
If **EMPAMAK** is stopped earlier than your doctor has prescribed, your blood sugar levels may increase. Always take **EMPAMAK** for as long as your doctor has prescribed.

4 Possible side effects

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

If any of the following happens, stop taking **EMPAMAK** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Any sign of an allergic reaction (hypersensitivity) such as skin rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, and wheezing and shortness of breath.

- Any sign of ketoacidosis such as
- Increased levels of “ketone bodies” in your urine or blood
- Rapid weight loss
- Feeling sick or being sick
- Stomach pain
- Excessive thirst
- Fast and deep breathing
- Confusion
- Unusual sleepiness or tiredness
- A sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat

This may occur regardless of your blood glucose (sugar) level. Your doctor may decide to temporarily or permanently stop your treatment with **EMPAMAK**. Please see also the section “Take special care with **EMPAMAK**.”

These are all very serious side effects. If you have them, you may have had a serious reaction to **EMPAMAK**. You may need urgent medical attention or hospitalisation.
Contact your doctor as soon as possible if you notice the following side effects:
- Low blood sugar (hypoglycaemia), seen frequently when taking **EMPAMAK** with sulphonylurea or with insulin.

The signs of low blood sugar may include:
- Jitteriness, sweating, feeling very anxious or confused, fast heart beat
- Excessive hunger, headache.

Talk to your doctor or other healthcare professional about how to recognise, manage and prevent low blood sugar (hypoglycaemia). If you have symptoms of low blood sugar, eat a high sugar snack or drink juice or soda which contains sugar. Measure your blood sugar if possible and rest.
- Urinary tract infection, seen frequently:

The signs of urinary tract infection are:
- Burning sensation when passing urine
- Urine that appears cloudy
- Pain in the pelvis, or mid-back pain, sometimes with fever, nausea or vomiting (when the kidneys are infected).

The signs of an urge to pass urine or more frequent urination may be due to the way **EMPAMAK** works, however as they can also be signs of a urinary tract infection, you should contact your doctor if you note an increase in such symptoms. Serious urinary tract infections that can lead to hospitalisation may occur.
- Dehydration (excessive loss of fluid from your body) seen less frequently. The signs of dehydration are not specific, however, may include:
  - Unusual thirst
  - Light-headedness or dizziness upon standing
  - Fainting or loss of consciousness

Tell your doctor if you notice any of the following:
Frequent
- Genital infection and genital yeast infection (especially in women)
- Urinary tract infection
- Weight loss
- Low blood sugar
- Thirst
- Constipation
- Itching and rash
- Passing more urine than usual or needing to pass urine more often
- Increased blood fats (lipids)

Less frequent
- Skin rash
- Swelling of the skin
- Straining or pain when emptying the bladder
- Increase in test results for:
  - Blood creatinine (a chemical waste molecule which is generated from your metabolism process)
  - Volume of red blood cells in your blood (haematocrit)

Frequency unknown
- Necrotising fasciitis of the perineum or Fournier's gangrene, a serious soft tissue infection of the genitals or the area between the genitals and the anus
- Diabetic ketoacidosis: a serious complication of diabetes that occurs when your body produces high levels of blood acids called ketones. The condition develops when your body can't produce enough insulin.
- 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 **EMPAMAK**, please consult your healthcare provider for advice.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA and eReporting platform (whi-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **EMPAMAK.**

5. How to store EMPAMAK

Store at or below 30 °C.
KEEP 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 EMPAMAK contains
The active ingredient is empagliflozin.
Contains sugar - lactose monohydrate
The other ingredients are:
Microcrystalline cellulose
Lactose monohydrate
Croscarmellose sodium
Hydroxypropyl cellulose
Colloidal silicon dioxide
Magnesium stearate
Instacoat universal yellow
- Hypromellose 6 cPs
- Polyethylene glycol 400
- Talc
- Titanium dioxide
- Yellow iron oxide

What EMPAMAK looks like and contents of the pack
EMPAMAK 10: Each film-coated tablet contains 10 mg of Empagliflozin.
EMPAMAK 25: Each film-coated tablet contains 25 mg of Empagliflozin.

Contents of the pack:
Tablets are packed in Plain 25µ aluminium foil with 6-8 gsm heat seal lacquer coating/ Clear PVC 250µ film on the other side. Pack size include10's & 30's tablets.
Not all pack sizes may be marketed.

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 17 June 2025

Registration numbers
EMPAMAK 10 : 56/21.2/1147
EMPAMAK 25 : 56/21.2/1148

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

335 mm

Back Side

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

EMPAMAK 10 mg (filmbedekte tablet)
Bevat empagliflosin 10 mg
Bevat suiker (42,4 mg van laktosemonohidraat).
EMPAMAK 25 mg (filmbedekte tablet)
Bevat empagliflosin 25 mg
Bevat suiker (106,0 mg van laktosemonohidraat).

Lees hierdie hele inligtingstuk noukeurig deur voordat jy EMPAMAK 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.
- **EMPAMAK** 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 EMPAMAK is en waarvoor dit gebruik word**
2. **Wat jy behoort te weet voordat jy EMPAMAK neem**
3. **Hoe om EMPAMAK te neem**
4. **Moontlike newe-effekte**
5. **Hoe om EMPAMAK te bewaar**
6. **Inhoud van die pak en ander inligting**

Moet nie EMPAMAK neem as jy 'tipe 1' diabetes het nie.
EMPAMAK word nie gebruik om liggaamsgewig te beheer nie.
Daar was berigte van 'metaboliese asidose' of 'ketoasidose' in persone met diabetes mellitus wat EMPAMAK neem, wat lewensgevaarlik is en in die hospitaal behandel moet word. Gevalle van ketoasidose is ook aangemeld in mense sonder diabetes mellitus.
Indien jy enige simptome van metaboliese asidose het, soos siek voel of siek wees, maagpyn, oormatige dors, vinnige en diep asemhaling, verwarring, ongewone slaperigheid of moegheid, 'n soet reuk aan jou asem, 'n soet of metaalagtige smaak in jou mond, of 'n vreemde reuk aan jou uriene of sweet, moet jy onmiddellik 'n dokter of die naaste hospitaal kontak om vir metaboliese asidose geassesseer te word, selfs al is jou bloedglukosevlak onder 11 mmol/L.
Verwys asseblief ook na Waarskuwings en voorsorgmaatreëls.

1. Wat EMPAMAK is en waarvoor dit gebruik word

EMPAMAK bevat empagliflosin.
EMPAMAK word gebruik om 'tipe 2-diabetes' in volwassenes (ouderdom 18 jaar en ouer) te behandel om bloedsuikerbeheer (glukose) saam met dieet en oefening te verbeter. **EMPAMAK** moet nie gebruik word om jou bloedsuiker te beheer indien jy matige of ernstige nierprobleme het nie.
EMPAMAK is 'n medisyne wat per mond geneem word om hoë bloedsuikervlakke te behandel. Die aktiewe bestanddeel in **EMPAMAK**, empagliflosin, werk deur 'n proteïen in die niere, genaamd natriumglukose-ko-transporter 2 (SGLT2), te blokkeer.

EMPAMAK mag nie in persone met 'tipe 1-diabetes' gebruik word nie.
EMPAMAK kan alleen gebruik word of kan ook saam met ander medisyne geneem word wat gebruik word om jou bloedsuiker te verlaag. Hierdie kan medisyne wees wat per mond geneem word of insulien wat deur inspuiting gegee word.

As gevolg van hoe **EMPAMAK** werk, sal jou uriene positief toets vir suiker terwyl jy **EMPAMAK** neem. Jou bloedsuikerbeheer kan om die rede nie geassesseer word deur gebruik te maak van die teenwoordigheid van suiker (glukose) in jou uriene, om jou bloedsuiker te monitor nie.

Dit is belangrik om die advies oor dieet en oefening te volg wat jy deur jou professionele gesondheidswerker gegee is.

2. Wat jy behoort te weet voordat jy EMPAMAK neem

Moet nie EMPAMAK neem nie:
- indien jy allergies is vir empagliflosin of enige van die ander bestanddele van hierdie medisyne (gelys in **afdeling 6**)
- Indien jy tipe 1-diabetes het
- Indien jy verhoogde vlakke van ketoonliggame in jou uriene of bloed het.
- Indien jy ernstige nierprobleme het, of nierversaking het en op nierdialise is.
- Indien jy swanger is of indien jy jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **EMPAMAK**
Ketoasidose: Indien jy vinnige gewigsverlies ervaar, siek voel of siek is, maagpyn, oormatige dors, vinnige en diep asemhaling, verwarring, ongewone slaperigheid of moegheid, 'n soet reuk aan jou asem, 'n soet of metaalagtige smaak in jou mond, of 'n vreemde reuk aan jou uriene of sweet het, kontak onmiddellik 'n dokter of die naaste hospitaal. Hierdie simptome kan 'n teken wees van "ketoasidose" - 'n seldsame, maar ernstige, soms lewensgevaarlike probleem wat jy met diabetes kan kry as gevolg van verhoogde vlakke van "ketoonliggame" in jou uriene of bloed, gesien in toetse. Die risiko om ketoasidose te ontwikkel, kan verhoog word met langdurige vas, oormatige alkoholverbruik, dehidrasie, skielike vermindering in insuliendosis, of 'n verhoogde behoefte aan insulien as gevolg van groot chirurgie of ernstige siekte.
- Indien jy "tipe 1-diabetes" het. Hierdie tipe begin gewoonlik wanneer jy jonk is en jou liggaam geen insulien produseer nie. Jy moet nie **EMPAMAK** neem om jou tipe 1-diabetes te behandel nie.
- Indien jy ernstige nier- of lewerprobleme het – jou dokter kan jou vra om 'n ander medisyne te neem.
- Daar kan 'n risiko van dehidrasie wees, byvoorbeeld:
  - Indien jy siek is, diarree of koors het, of indien jy nie kan eet of drink nie
  - indien jy medisyne neem wat urienproduksie verhoog [diuretika] of bloeddruk verlaag
  - Indien jy ouer as 75 jaar oud is. Moontlike tekens word in **afdeling 4** onder 'dehidrasie' gelys. Jou dokter kan jou vra om op te hou om **EMPAMAK** te neem totdat jy herstel om verlies van te veel liggaamsvloeistof te verhoed. Vra oor maniere om dehidrasie te verhoed.
- Indien jy 85 jaar oud of ouer is, aangesien jy nie **EMPAMAK** moet begin neem nie as gevolg van beperkte terapeutiese ervaring
- Indien jy 'n ernstige infeksie van die nier of die urienweg met koors het. Jou dokter kan jou vra om op te hou om **EMPAMAK** te neem totdat jy herstel het.
- Praat onmiddellik met jou dokter indien jy 'n kombinasie van simptome van pyn, teerheid, rooiheid, of swelling van die geslagsdele of die area tussen die geslagsdele en die anus ontwikkel, met koors of voel oor die algemeen sleg. Hierdie simptome kan 'n teken wees van 'n seldsame maar ernstige of selfs lewensgevaarlike infeksie, naamlik nekrotiserende fassitis van die perineum of Fournier se gangreen wat die weefsel onder die vel vernietig. Fournier se gangreen moet onmiddellik behandel word.
- Voetversorging: Soos vir alle diabetiese pasiënte, is dit belangrik om jou voete gereeld na te gaan en te hou by enige ander advies rakende voetversorging wat deur jou professionele gesondheidsorgwerker gegee word.
- Nierfunksie: Jou niere moet nagegaan word voordat jy begin om hierdie medisyne te neem en terwyl jy op dit is.
- Urienglukose: As gevolg van hoe hierdie medisyne werk, sal jou uriene positief toets vir suiker terwyl jy hierdie medisyne neem.

Kinders en adolessente
EMPAMAK word nie aanbeveel vir kinders en adolessente jonger as 18 jaar nie, omdat dit nie in hierdie pasiënte bestudeer is nie.
Ander medisyne en EMPAMAK
Vertel altyd jou professionele gesondheidsorgwerker indien jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker indien jy enige van die volgende medisyne neem:
- Indien jy medisyne neem wat urienproduksie verhoog (diuretika). Jou dokter kan jou vra om op te hou om **EMPAMAK** te neem. Moontlike tekens van die verlies van te veel vloeistof vanuit jou liggaam word in **afdeling 4** gelys.
- Indien jy ander medisyne neem wat die hoeveelheid suiker in jou bloed verlaag, soos insulien of 'n "sulfonielureum" medisyne. Jou dokter mag dalk die dosis van hierdie ander medisyne verlaag om te verhoed dat jou bloedsuikervlakke te laag daal (hipoglukemie).

EMPAMAK met kos en vloeistowwe en alkohol:
- Jy kan **EMPAMAK** met of sonder kos neem.

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. Moet nie **EMPAMAK** gebruik as jy swanger is nie. Dit is onbekend of **EMPAMAK** skadelik is vir die ongebore kind. Moet nie **EMPAMAK** gebruik indien jy borsvoed nie. Dit is nie bekend of **EMPAMAK** in menslike borsmelk oorgaan nie.

Bestuur en gebruik van masjinerie
EMPAMAK het 'n geringe invloed op die vermoë om te bestuur en om masjinerie te gebruik. Neem van hierdie medisyne in kombinasie met medisyne wat sulfonielureun genoem word, of met insulien, kan veroorsaak dat bloedsuikervlakke te laag daal (hipoglukemie), wat simptome soos bewe, sweet en verandering in visie kan veroorsaak, en kan jou vermoë om te bestuur en masjinerie te gebruik beïnvloed. Moet nie bestuur of enige gereedskap of masjiene gebruik indien jy duiselig voel terwyl jy **EMPAMAK** neem nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **EMPAMAK** met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waartoe **EMPAMAK** hulle affekteer nie.

EMPAMAK bevat laktose
Pasiënte met die seldsame oorerflike toestande van laktose- of galaktose-intoleransie moet nie **EMPAMAK** neem nie.

3. Hoe om EMPAMAK te neem

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

Neem altyd **EMPAMAK** presies soos wat jou dokter vir jou opdrag gegee het. Bevestig met jou dokter of apteker indien jy nie seker is nie.

Die aanbevole aanvangsdosis van **EMPAMAK** is een 10 mg tablet een keer per dag. Jou dokter kan jou aansê om die dosis tot 25 mg een keer per dag te verhoog, indien jou bloedglukose nie voldoende beheer word met 'n dosis van 10 mg per dag nie.
Jou dokter sal die sterkte voorskryf wat reg is vir jou. Moet nie jou dosis verander nie, tensy jou dokter jou aangesê het om dit te doen.

Metode van toediening
Sluk die tablet heel met water. Jy kan die tablet met of sonder kos neem. Jy kan die tablet enige tyd van die dag neem. Probeer egter om dit elke dag op dieselfde tyd te neem. Dit sal jou help om te onthou om dit te neem.

Gaan voort om **EMPAMAK** te neem solank jou dokter dit voorskryf sodat jy kan voortgaan om jou bloedsuiker te help beheer. Jou dokter kan **EMPAMAK** saam met ander medisyne vir diabetes voorskryf. Onthou om alle medisyne te neem soos deur jou dokter voorgeskryf om die beste resultate vir jou gesondheid te behaal.

Dieet en oefening kan ons liggaam help om sy bloedsuiker beter te gebruik. Dit is belangrik om te bly op die dieet en oefenprogram wat deur jou professionele gesondheidsorgwerker aanbeveel word terwyl jy **EMPAMAK** neem.
Kontroleer jou bloedsuiker soos jou professionele gesondheidsorgwerker jou sê hoe om te doen.
Indien jy die indruk kry dat die effek van **EMPAMAK** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer EMPAMAK 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.

Indien jy vergeet om EMPAMAK te neem
Dit is belangrik om jou **EMPAMAK** gereeld op dieselfde tyd elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit sodra jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. Moet nie 'n dubbele dosis neem, om op te maak vir 'n vergete dosis nie. Moet nooit twee dosisse op dieslefde dag neem nie.

Indien jy ophou om EMPAMAK te neem
Wanneer **EMPAMAK** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou bloedsuikervlakke verhoog. Neem altyd **EMPAMAK** vir solank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

EMPAMAK kan newe-effekte hê.
Nie alle newe-effekte wat vir **EMPAMAK** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **EMPAMAK** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **EMPAMAK** te neem en kontak onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- Enige teken van 'n allergiese reaksie (hipersensitiwiteit) soos veluitslag, galbulte en swelling van die gesig, lippe, tong en keel wat probleme met asemhaling of sluk kan veroorsaak, en asemgefluit en kort van asem.
- Enige teken van ketoasidose soos
  - Verhoogde vlakke van "ketoonliggame" in jou uriene of bloed
  - Vinnige gewigsverlies
  - Voel siek of is siek
  - Maagpyn
  - Oormatige dors
  - Vinnige en diep asemhaling
  - Verwarring
  - Ongewone slaperigheid of moegheid
  - 'n Soet reuk aan jou asem, 'n soet of metaalagtige smaak in jou mond of 'n vreemde reuk aan jou uriene of sweet

Dit kan voorkom ongeag jou bloedglukose (suiker) vlak. Jou dokter kan besluit om jou behandeling met **EMPAMAK** tydelik of permanent te staak. Sien asseblief ook die afdeling "Neem spesiale sorg met **EMPAMAK**."

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige reaksie op **EMPAMAK** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.
Kontak jou dokter so gou as moontlik indien jy die volgende newe-effekte opmerk:
- Lae bloedsuiker (hipoglukemie), wat gereeld gesien word wanneer **EMPAMAK** saam met sulfonielureum of met insulien geneem word.

Die tekens van lae bloedsuiker kan die volgende insluit:
- Gejaagdheid, sweet, baie angstig of verward voel, vinnige hartklop
- Oormatige honger, hoofpyn.

Praat met jou dokter of ander professionele gesondheidsorgwerker oor hoe om lae bloedsuiker (hipoglukemie) te herken, te bestuur en te verhoed. Indien jy simptome van lae bloedsuiker het, eet 'n hoë suikerhappie of drink sap of koeldrank wat suiker bevat. Meet jou bloedsuiker indien moontlik en rus.
- Urienweginfeksie, gereeld gesien:

Die tekens van urienweginfeksie is:
- Brandende sensasie wanneer jy urineer
- Uriene wat troebel lyk
- Pyn in die bekken, of pyn in die middel van die rug, soms met koors, naarheid of braking (wanneer die niere geinfekteer is).

Die tekens van 'n drang om te urineer of meer gereelde urinering kan wees as gevolg van die wyse waarop **EMPAMAK** werk, maar omdat dit ook tekens van 'n urienweginfeksie kan wees, moet jy jou dokter kontak indien jy 'n toename in sulke simptome opmerk. Ernstige urienweginfeksies wat tot hospitalisering kan lei, kan voorkom.
- Dehidrasie (oormatige verlies aan vloeistof vanuit jou liggaam) minder gereeld gesien. Die tekens van dehidrasie is nie spesifiek nie, maar kan die volgende insluit:
  - Ongewone dors
  - Lighoofdigheid of duiseligheid wanneer jy opstaan
  - Floute of verlies van bewussyn

Vertel jou dokter as jy enige van die volgende opmerk:
Gereeld
- Infeksie van die geslagsdele en genitale gisinfeksie (veral in vroue)
- Urienweginfeksie
- Gewigsverlies
- Lae bloedsuiker
- Dors
- Hardlywigheid
- Gejeuk en uitslag
- Passeer meer uriene as gewoonlik of moet meer gereeld urineer
- Verhoogde bloedvette (lipiede)

Minder gereeld
- Veluitslag
- Swelling van die vel
- Inspanning of pyn wanneer die blaas leeggemaak word
- Verhoging in toetsresultate vir:
  - Bloedkreatinien ('n chemiese afvalmolekule wat uit jou metabolismeproses gegenereer word)
  - Volume van rooibloedselle in jou bloed (hematokrit)

Frekwensie onbekend
- Nekrotiserende fassitis van die perineum of Fournier se gangreen, 'n ernstige sagteweefselinfeksie van die geslagsdele of die area tussen die geslagsdele en die anus
- Diabetiese ketoasidose: 'n ernstige komplikasie van diabetes wat voorkom wanneer jou liggaam hoë vlakke van bloedsure naamlik ketone, produseer. Die toestand ontwikkel wanneer jou liggaam nie genoeg insulien kan produseer nie.
- 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 verswak of indien jy enige ongunstige effekte ervaar terwyl jy **EMPAMAK** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **EMPAMAK.**

5. Hoe om EMPAMAK te bewaar

Bewaar by of benede 30 °C.
HOU BUITE DIE BEREIK VAN KINDERS.
Bewaar in die oorspronklike verpakking / houer.
Hou die stulpstroke in die karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die stulptrook / etiket / karton / bottel aangedui word nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat EMPAMAK bevat
Die aktiewe bestanddeel is empagliflosin.
Bevat suiker - laktosemonohidraat
Die ander bestanddele is:
Mikrokristallyne sellulose
Laktosemonohidraat
Natriumkuiskarmellose
Hidroksipropielsellulose
Kolloïdale silikondioksied
Magnesiumstearaat
Instacoat universal geel
- Hipromellose 6 cPs
- Poliëtileen glikol 400
- Talk
- Titaandioksied
- Geel ysteroksied

Hoe EMPAMAK lyk en inhoud van die pak
EMPAMAK 10: Elke filmbedekte tablet bevat 10 mg Empagliflosin.
EMPAMAK 25: Elke filmbedekte tablet bevat 25 mg Empagliflosin.

Inhoud van die pak:
Tablette word verpak in gewone 25µ aluminiumfoelie met 6-8 gsm hitteseël laklaag / deursigtige PVC 250µ film aan die ander kant. Pakgrootte sluit in 10's & 30's tablette.
Nie alle verpakkingsgroottes word noodwendig bemark word nie.

HOUER VAN SERTIFIKAAT VAN REGISTRASIE
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1,
Bassonia Estate Kantoorpark (Oos),
1 Cussonia-rylaan ,
Bassonia Rock, Uitbr. 12,
Alberton
Gauteng

Hierdie inligtingstuk was laas hersien in 17 June 2025

Registrasienommers
EMPAMAK 10: 56/21.2/1147.
EMPAMAK 25: 56/21.2/1148.

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

350 mm

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: EMPAMAK 10/25 (Empagliflozin Tablet 10 mg and 25 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: 350 (L) x 335 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM04340735**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40708 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No:**
15. Revision No: 00	**16. A/W File name:Z:\South Africa\Empagliflozin\SA Private Market\Empagliflozin Tablet 10 -20 mg PIL - PM04340735.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	04/02/2026				

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/021/04-01

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa (Private Market)	PM04340735		