

**DR. REDDY'S LABORATORIES (PTY) LTD.
INGLYFLO 10 and INGLYFLO 25
FILM-COATED TABLETS
APPROVED PATIENT INFORMATION LEAFLET**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

INGLYFLO 10

INGLYFLO 25

Empagliflozin

Film-coated tablets

Contains sugar (lactose anhydrous):

Each INGLYFLO 10 film-coated tablet contains 20,5 mg lactose anhydrous

Each INGLYFLO 25 film-coated tablet contains 51,4 mg lactose anhydrous

Contains sodium

Read all of this leaflet carefully before you start taking INGLYFLO

- 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.
- INGLYFLO 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.

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INGLYFLO is used together with diet and exercise to lower blood sugar in adults with type 2 diabetes only.

Do not take INGLYFLO if you have type 1 diabetes.

INGLYFLO is not used to control body weight.

There have been reports of metabolic acidosis or ketoacidosis in people taking INGLYFLO which is life-threatening and needs to be treated in hospital.

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 to "Take special care with INGLYFLO".

What is in this leaflet

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

1. What INGLYFLO is and what it is used for

INGLYFLO contains the active substance empagliflozin which is a member of the group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors. INGLYFLO works by blocking the SGLT2 protein in your kidneys. This causes blood sugar (glucose) to be removed in your urine, thereby lowering the amount of sugar in your blood.

INGLYFLO is used:

- To treat type 2 diabetes in adult patients (aged 18 years and older) to improve blood sugar

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(glucose) control together with diet and exercise.

- INGLYFLO is also used in adults with 'type 2 diabetes' with an increased cardiovascular risk (health problems due to your heart and blood vessels), to lower the risk of dying from a heart attack or other events related to your heart or blood vessels

Type 2 diabetes is a disease where your body is able to produce insulin, but your cells don't respond to insulin the way they should. Type 2 diabetes is also known as non-insulin-dependent diabetes.

It is important that you continue with your diet and exercise plan as told by your doctor, pharmacist or nurse.

INGLYFLO tablets are not recommended for use in combination with other antidiabetic medicines and for treatment of chronic kidney disease and heart failure. However, it is recommended to use another suitable medicine containing empagliflozin for the same.

2. What you need to know before you take INGLYFLO

Do not take INGLYFLO if you:

- are hypersensitive (allergic) to empagliflozin or to any of the other ingredients of INGLYFLO (see list under section 6).
- have Type 1 diabetes (insulin-dependent diabetes, causing high sugar levels in your blood).
- If you have increased levels of ketone bodies in your urine or blood (see "Take special care with INGLYFLO")
- if you have moderate or severe kidney problems, or have kidney failure and are on kidney dialysis
- if you are pregnant or are breastfeeding your baby.

If any of the above applies to you, do not take INGLYFLO and talk to your doctor.

Warnings and precautions

Take special care with INGLYFLO.

Talk to your doctor, pharmacist or nurse before taking INGLYFLO, and during treatment with INGLYFLO 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

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or metallic taste in your mouth, or a different odour to your urine or sweat; contact your doctor or the nearest hospital immediately. These symptoms could be a sign of diabetic 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 diabetic 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.

- have serious kidney or liver problems – your doctor may prescribe you a different medicine. Your kidney function should be assessed before you start taking INGLYFLO, at least 6-monthly during treatment.
- have a history of urinary tract infections or have a serious infection of the kidneys or urine. Your doctor may ask you to stop taking INGLYFLO until you have recovered.

If any of the following apply to you, you may be at risk of dehydration:

- ✓ being sick, have diarrhoea or fever, or if you are not able to eat or drink
- ✓ taking medicine that increase urine production (diuretics) or lower blood pressure
- ✓ are over 75 years old.

Possible signs are listed in section 4 under “dehydration”. Your doctor may ask you to stop taking INGLYFLO until you recover to prevent loss of too much body fluids.

Ask about ways to prevent dehydration:

- If you are 85 years old or older as you should not start taking INGLYFLO.
- If you have a serious infection of the kidneys or the urinary tract with fever. Your doctor may ask you to stop taking INGLYFLO 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.

Please also make a note if you have symptoms of genital burning, redness, pain and discharge which may

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be signs of a genital infection.

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 provider.

Urine glucose:

Because of how INGLYFLO works, your urine will test positive for sugar while you are taking INGLYFLO.

Children and adolescents

INGLYFLO is not recommended for children and adolescents under 18 years of age, because it has not been studied.

Other medicines and INGLYFLO

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

The following medicines may cause an interaction when taken in combination with INGLYFLO:

- Medicines used to remove water from your body (diuretics, also called “water tablets”). Your doctor may ask you to stop taking INGLYFLO. Possible signs of losing too much fluid from your body are listed in section 4.
- Lithium (a mood stabilising medicine), because INGLYFLO can lower the amount of lithium in your blood.

INGLYFLO with food, drink and alcohol

You can take INGLYFLO with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

Do not take INGLYFLO if you are pregnant or breastfeeding.

Driving and using machines

INGLYFLO has minor influence on the ability to drive a vehicle and use machines.

Do not perform any tasks requiring your attention if you feel dizzy while taking INGLYFLO.

INGLYFLO contains lactose

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If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking INGLYFLO.

INGLYFLO contains sodium

INGLYFLO contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take INGLYFLO

Do not share medicines prescribed for you with any other person. Always take INGLYFLO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Dosage and frequency

The usual dose of INGLYFLO is one 10 mg film-coated tablet once a day. Your doctor will decide whether to increase your dose to 25 mg once a day.

Your doctor will prescribe the strength that is right for you.

Do not change your dose unless your doctor has told you to.

Check your blood sugar as your healthcare professional advises you to.

Appropriate diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise program recommended by your healthcare provider while taking INGLYFLO.

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 INGLYFLO as long as your doctor prescribes it.

If you have the impression that the effect of INGLYFLO is too strong or too weak, tell your doctor or pharmacist.

If you take more INGLYFLO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take INGLYFLO

If you forget to take a dose of INGLYFLO, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

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Never take two doses on the same day.

If you stop taking INGLYFLO

Do not stop taking INGLYFLO without first consulting your doctor. Your blood sugar levels may increase when you stop taking INGLYFLO.

4. Possible side effects

INGLYFLO can have side effects.

Not all side effects reported for INGLYFLO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INGLYFLO, please consult your health care provider for advice.

If any of the following happens to you, stop taking INGLYFLO and tell your doctor immediately, or go to the casualty department at your nearest hospital as you will need immediate medical attention or hospitalisation:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to INGLYFLO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Signs of diabetic ketoacidosis which includes:
 - ✓ increased levels of ketone bodies in your urine or blood,
 - ✓ rapid weight loss,
 - ✓ nausea or vomiting,
 - ✓ stomach pain,

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- ✓ 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 blood glucose level. Your doctor may decide to stop your treatment with INGLYFLO temporarily or permanently.

- Low blood sugar (hypoglycaemia) with the following symptoms:
 - ✓ shaking, sweating, feeling very anxious or confused, fast heartbeat,
 - ✓ excessive hunger, headache.

Your doctor will tell you how to treat low blood sugar levels and what to do if you get any of the signs above.

If you have symptoms of low blood sugar, eat glucose tablets, a high sugar snack or drink fruit juice.

Measure your blood sugar if possible and rest.

- Dehydration, including the following signs:
 - ✓ unusual thirst,
 - ✓ light-headedness or dizziness upon standing,
 - ✓ fainting or loss of consciousness.
- 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.
- Urinary tract infection, including the following signs:
 - ✓ 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).

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

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Tell your doctor if you notice any of the following:

Frequent side effects

- Genital yeast infection (thrush).
- An urge to pass urine or more frequent urination may be due to the way INGLYFLO works, but they can also be signs of urinary tract infection. If you note an increase in such symptoms, you should contact your doctor.
- Itching.
- Constipation.
- Rash or red skin – this may be itchy and include raised bumps, oozing fluid or blisters.
- Thirst.
- Blood tests may show an increase in cholesterol levels in your blood.
- Weight loss.
- Glucose in the urine.

Less frequent side effects

- Hives.
- Straining or pain when emptying the bladder.
- Blood tests may show a decrease in kidney function (creatinine or urea).
- Blood tests may show increases in the amount of red blood cells in your blood (haematocrit).
- Ketones in the urine.
- Decrease in kidney filtration rate.
- inflammation of the kidneys (tubulointerstitial nephritis).
- Tight foreskin of the penis.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of INGLYFLO.

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5. How to store INGLYFLO

Store at or below 25 °C.

Keep in the original packaging until required for use.

Do not store in bathrooms.

Do not use after the expiry date stated on the containers/labels.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g., toilets).

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information

What INGLYFLO contains

The active substance is empagliflozin.

INGLYFLO 10: Each film-coated tablet contains 10 mg empagliflozin.

INGLYFLO 25: Each film-coated tablet contains 25 mg empagliflozin.

The other ingredients are lactose anhydrous, croscarmellose sodium, hydroxypropyl cellulose, isopropyl alcohol, colloidal silicon dioxide, magnesium stearate and Opadry White (containing hypromellose, titanium dioxide, propylene glycol, talc, iron oxide yellow).

What INGLYFLO looks like and contents of the pack

INGLYFLO 10: Pale yellow coloured, round shaped, film-coated tablets debossed with "ME" on one side and "3" on the other side.

INGLYFLO 25: Pale yellow coloured, round shaped, film-coated tablets debossed with "ME4" on one side and plain on the other side.

INGLYFLO is packed in:

Silver aluminium/PVC/PVdC blister strips containing 10 tablets each and placed in an outer carton. Pack sizes: 10 or 30 tablets.

Or:

White opaque, 40 cc high-density polyethylene (HDPE) bottle with 33 mm child-resistant closure. Pack sizes: 30 or 90 tablets.

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Not all strengths and pack sizes may be marketed.

Holder of Certificate of Registration

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For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration: Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:
<http://www.drreddys.co.za>