

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TAPLEO® 5 (Tablet)

TAPLEO® 10 (Tablet)

Dapagliflozin

Contains sugar:

25 mg lactose anhydrous per 5mg tablet

50 mg lactose anhydrous per 10mg tablet

DO NOT USE TAPLEO IF YOU HAVE TYPE 1 DIABETES.

There have been reports of metabolic acidosis, including ketoacidosis, in patients taking TAPLEO.

Metabolic acidosis is an imbalance of acids in your blood, shown on blood tests. It is a serious and sometimes fatal condition that requires hospitalisation. 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 TAPLEO 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 TAPLEO 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 TAPLEO.

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 volumes of urine, shortness of breath and confusion. These symptoms could be a sign of metabolic or diabetic ketoacidosis.

Read all of this leaflet carefully before you start taking TAPLEO.

- 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
- TAPLEO 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 TAPLEO is and what it is used for
2. What you need to know before you take TAPLEO
3. How to take TAPLEO
4. Possible side effects

5. How to store TAPLEO

6. Contents of the pack and other information

1. What TAPLEO is and what it is used for:

TAPLEO contains the active substance dapagliflozin. It belongs to a group of medicines called “oral anti-diabetics”. These are medicines taken by mouth for diabetes.

- TAPLEO is used if your type 2 diabetes cannot be controlled with different medicines for diabetes, diet and exercise.
- Your doctor may ask you to take TAPLEO alone or with another diabetes medicines.
- TAPLEO increases the amount of sugar excreted by your kidneys.
- TAPLEO is also used for prevention and treatment of heart failure (when the heart does not pump enough blood that the body needs).

TAPLEO is not recommended for children and young people under 18 years.

It is important to keep following the advice about diet and exercise given to you by your doctor, nurse or pharmacist.

2. What you need to know before you take TAPLEO:

Do not take TAPLEO:

- if you are allergic (hypersensitive) to dapagliflozin or any of the other ingredients of TAPLEO (listed in “What TAPLEO contains”). If you are not sure, talk to your doctor or pharmacist before taking this medicine.
- if you have moderate or severe kidney disease or you are on dialysis.
- if you have type 1 diabetes – the type that usually starts when you are young, and your body does not produce any insulin.
- if you are pregnant or plan to become pregnant. Talk with your doctor about the best way to control your blood sugar while you are pregnant.
- if you are breast-feeding. Talk to your doctor if you would like to breast-feed your baby.

Warnings and precautions:

Take special care with TAPLEO:

- if you are going to have 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 urine or blood. 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 TAPLEO.

Other medicines and TAPLEO:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor:

- if you are taking ketoconazole (medication for fungal infections).
- if you are taking a water pill (diuretic) – you may be more likely to lose fluid from your body (get dehydrated). Your doctor may change your dose. Possible signs of losing too much fluid from your body are listed in Section 4 “Possible Side Effects”.
- if you are taking other medicines that lower the amount of sugar in your blood - such as insulin or a “sulfonylurea” medicine. Your doctor may want to lower your dose of these other medicines, to stop you from getting low blood sugar (hypoglycaemia).

Pregnancy and breastfeeding:

You should not take TAPLEO if you are pregnant or breastfeeding your baby. 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 healthcare provider for advice before taking/ receiving TAPLEO.

Driving and using machines:

Taking TAPLEO with other medicines or insulin used to treat your diabetes 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 while taking TAPLEO. It is not always possible to predict to what extent TAPLEO may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of how TAPLEO affects them.

Important information about some of the ingredients of TAPLEO:

TAPLEO contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take TAPLEO.

3. How to take TAPLEO:

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

Always take TAPLEO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take:

- The usual dose is one 10 mg tablet each day.
- Your doctor will prescribe the strength that is right for you.
- Your doctor will tell you how long your treatment with TAPLEO will last.
- Do not stop treatment early.
- If you have the impression that the effect of TAPLEO is too strong or too weak for you, tell your doctor or pharmacist.

Taking this medicine:

- Swallow the tablet whole with some water.
- You can take your 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.

Your doctor may prescribe TAPLEO together with other medicines to lower the amount of sugar in your blood.

Use in children:

TAPLEO is not recommended for children or young people under 18 years old.

Diet and exercise:

To control your diabetes, you still need to diet and exercise, even when you are taking this medicine. So, it is important to keep following the advice about diet and exercise from your health care professional. In particular, if you are following a diabetic weight control diet, keep on with this while you are taking TAPLEO.

If you take more TAPLEO than you should:

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

If you forget to take TAPLEO:

Take your missed dose as soon as you remember, if within a few hours after missing a dose. However, if it is nearly time for your next dose, skip the missed dose. Then take

your next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TAPLEO:

Do not stop taking TAPLEO without talking to your doctor first. If you have the impression that the effect of TAPLEO is too strong or too weak, talk to your doctor or pharmacist.

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.

TAPLEO can have side effects.

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

If you have a hypersensitivity (allergic) reaction, stop taking TAPLEO 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 side effects:

- 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 heart beat
- 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.

- yeast infection (thrush) of your penis or vagina

- 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.
- changes in the amount of red blood cells in your blood (shown in tests)
- infection of the bladder
- rash

Less frequent side effects:

- awakening from sleep at night to pass urine
- change in amount of urea in blood (shown in tests)
- increased thirst and dry feeling of the mouth
- constipation
- itching of the genitals
- increase sweating
- tight foreskin which may cause difficulty urinating or inflammation of glans or foreskin (phimosis)

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. 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 TAPLEO.

5. How to store TAPLEO:

Store all medicines out of reach of children.

Store at or below 30 °C. Store in the original package.

Do not use TAPLEO after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information:

What TAPLEO contains:

- The active substance is dapagliflozin propanediol
- The other ingredients are:

Tablet core: crospovidone, lactose anhydrous, magnesium stearate, microcrystalline cellulose, silicon dioxide.

Film-coating: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, yellow iron oxide

What TAPLEO looks like and contents of the pack:

TAPLEO 5:

Yellow, biconvex, 0.7 cm diameter round, film-coated tablet with "5" debossed on one side and "1427" debossed on the other side.

TAPLEO 10:

Yellow, biconvex, approximately 1.1 x 0.8 cm diamond shaped, film-coated tablet with "10" debossed on one side and "1428" debossed on the other side.

Silver aluminium/aluminium foil blister packs of 14, 28, 30, 90 and 98 tablets packed in a carton. Not all pack sizes are marketed.

Holder of certificate of registration:

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