

Applicant : Sandoz SA (Pty) Ltd
Proprietary name : DAPAGLIFLOZIN 5 SANDOZ & 10
Dosage form and strength : Film-coated tablets. Each film-coated tablet contains dapagliflozin equal to 5 mg and 10 mg, respectively.

PATIENT INFORMATION LEAFLET

DAPAGLIFLOZIN 5 SANDOZ & DAPAGLIFLOZIN 10 SANDOZ

SCHEDULING STATUS: **S4**

DAPAGLIFLOZIN 5 SANDOZ (film-coated tablets)

DAPAGLIFLOZIN 10 SANDOZ (film-coated tablets)

Dapagliflozin

Contains sugar

Each DAPAGLIFLOZIN 5 SANDOZ film-coated tablet contains sugar (81,00 mg of lactose monohydrate).

Each DAPAGLIFLOZIN 10 SANDOZ film-coated tablet contains sugar (162,00 mg lactose monohydrate).

DO NOT USE DAPAGLIFLOZIN SANDOZ IF YOU HAVE TYPE 1 DIABETES.

DAPAGLIFLOZIN SANDOZ MUST NOT BE USED FOR THE TREATMENT OF ANY OTHER CONDITIONS EXCEPT TYPE 2 DIABETES.

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

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of the pancreas or previous pancreatic surgery. Do not use DAPAGLIFLOZIN SANDOZ 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 14 mmol/L) or high blood sugar levels who are treated with DAPAGLIFLOZIN SANDOZ.

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 DAPAGLIFLOZIN SANDOZ

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

1. What DAPAGLIFLOZIN SANDOZ is and what it is used for

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

- DAPAGLIFLOZIN SANDOZ 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 DAPAGLIFLOZIN SANDOZ alone or with another diabetes medicines.
- DAPAGLIFLOZIN SANDOZ is also used for prevention and treatment of heart failure (when the heart does not pump enough blood that the body needs).
- DAPAGLIFLOZIN SANDOZ 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 DAPAGLIFLOZIN SANDOZ

Do not take DAPAGLIFLOZIN SANDOZ

- if you are allergic (hypersensitive) to dapagliflozin or any of the other ingredients of DAPAGLIFLOZIN SANDOZ (listed in “What DAPAGLIFLOZIN SANDOZ 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.
- If you have a history of problems with your pancreas or had surgery on your pancreas.

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Warnings and precautions

Take special care with DAPAGLIFLOZIN SANDOZ:

- 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, difficulty breathing, increased levels of “ketone bodies” in your urine or blood, excessive thirst, confusion and tiredness. 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 have liver problems
- If your blood sugar levels are very high, as this may cause your body to dehydrate (lose too much water and salts).
- 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.

Tell your doctor or pharmacist immediately if you develop a combination of pain, tenderness, redness or swelling in your genital area or the area between the genitals and anus, with fever or a general unwell feeling. These symptoms could be a sign of a rare but serious infection called necrotising fasciitis of the perineum, or Fournier’s gangrene.

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

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As a diabetic patient, it is important to check your feet regularly and adhere to any other advice regarding foot care given to you by your doctor, pharmacist or other health care provider.

Due to the way DAPAGLIFLOZIN SANDOZ works, your urine will test positive for sugar while you are taking DAPAGLIFLOZIN SANDOZ.

Children and adolescents

DAPAGLIFLOZIN SANDOZ is not recommended for children and adolescents under 18 years of age, because it has not been studied in these patients.

Other medicines and DAPAGLIFLOZIN SANDOZ

Always tell your health care 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).
- if you are taking lithium because DAPAGLIFLOZIN SANDOZ can lower the amount of lithium in your blood.

Pregnancy and breastfeeding

You should not take DAPAGLIFLOZIN SANDOZ if you are pregnant or breastfeeding your baby.

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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 taking DAPAGLIFLOZIN SANDOZ.

Driving and using machines

DAPAGLIFLOZIN SANDOZ can cause dizziness. Taking DAPAGLIFLOZIN SANDOZ 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 DAPAGLIFLOZIN SANDOZ.

It is not always possible to predict to what extent DAPAGLIFLOZIN SANDOZ 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 DAPAGLIFLOZIN SANDOZ affects them.

DAPAGLIFLOZIN SANDOZ contains lactose monohydrate:

DAPAGLIFLOZIN SANDOZ contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DAPAGLIFLOZIN SANDOZ.

3. How to take DAPAGLIFLOZIN SANDOZ

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

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

- The usual dose is one 10 mg tablet each day.

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- Your doctor will prescribe the strength that is right for you.
- Your doctor will tell you how long your treatment with DAPAGLIFLOZIN SANDOZ will last.
- Your doctor may prescribe you DAPAGLIFLOZIN SANDOZ together with other medicines to lower your blood sugar levels.
- Your doctor will tell you how long your treatment with DAPAGLIFLOZIN SANDOZ will last. Do not stop treatment early.
- If you have the impression that the effect of DAPAGLIFLOZIN SANDOZ is too strong or too weak for you, tell your doctor or pharmacist.
- 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.

If you take more DAPAGLIFLOZIN SANDOZ 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 DAPAGLIFLOZIN SANDOZ

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 DAPAGLIFLOZIN SANDOZ

Do not stop taking DAPAGLIFLOZIN SANDOZ without talking to your doctor first. If you have any further questions on the use of DAPAGLIFLOZIN SANDOZ, ask your doctor or pharmacist.

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4. Possible side effects

DAPAGLIFLOZIN SANDOZ can have side effects.

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

If any of the following happens, stop taking DAPAGLIFLOZIN SANDOZ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing
- rash
- diabetic ketoacidosis (diabetic coma) (causing nausea (feeling sick), vomiting (being sick), pain in the stomach area, tiredness, thirst, passing of large volumes of urine, shortness of breath and confusion)
- necrotising fasciitis of the perineum (causing pain, tenderness, redness and swelling of the genital area or area between the genitals and anus, along with fever and a general unwell feeling)

These are all very serious side effects. If you have them, you may have had a serious reaction to DAPAGLIFLOZIN SANDOZ. 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:

- Very dry or sticky mouth, feeling very thirsty
- Feeling very sleepy or tired
- Passing little or no water (urine)

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- Fast heartbeat

These are signs of losing too much fluid from body (volume depletion or dehydration)

- Fever or chills
- Burning sensation when passing water (urinating)
- Pain in your back or side
- Blood in your urine

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:

- urinary tract infection (causing fever and/or chills, a burning sensation while urinating, an urge to frequently urinate, pain in your back or side and sometimes blood in your urine)
- low blood sugar levels, especially when taking DAPAGLIFLOZIN SANDOZ with insulin or a sulphonylurea (causing shaking, sweating, fast heartbeat, headache, changes in vision, a change in your mood and confusion)
- changes in test results when testing the amount of red blood cells in your blood
- changes in test results when testing the amount of cholesterol (fat) in your blood
- changes in test results when testing your kidney function,
- genital infections, including vaginal and penile thrush (causing irritation and itching in the area, discomfort while urinating and an increased amount of discharge) and inflammation of the penis glans (head) (causing tightness and redness of the skin, itching, irritation, an unpleasant smell and painful urination)
- high glucose (sugar) levels in the urine when tested
- painful or difficult urination, urinating more or more frequently than usual
- infection of the bladder

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- dizziness
- rash
- back pain

Less frequent side effects:

- changes in test results when testing your blood creatinine or urea levels
- decreased blood pressure
- urinating more frequently during the night
- genital itching
- thirst or a dry mouth
- constipation
- excessive sweating
- decreased weight
- 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, 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 DAPAGLIFLOZIN SANDOZ.

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Suspected side effects can also be reported directly to the Holder of the Certificate of

Registration (HCR) via: <https://pvi1j.solutions.igvia.com> or the e-mail address,

adverse.event.sac@sandoz.com.

5. How to store DAPAGLIFLOZIN SANDOZ

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Do not store above 25 °C.
- Do not use after the expiry date stated on the carton / blister.
- 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 DAPAGLIFLOZIN SANDOZ contains

The active substance is dapagliflozin. Each film-coated tablet contains 5 mg or 10 mg dapagliflozin.

Inactive ingredients:

Table core:

Hypromellose 2910, 3 mPas

Lactose Monohydrate

Microcrystalline Cellulose

Croscarmellose Sodium

Magnesium stearate

Film coating:

Hypromellose 2910, 6 mPas

Hydroxypropyl Cellulose

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Triethyl Citrate

Titanium Dioxide

Ferric Oxide Yellow

What DAPAGLIFLOZIN SANDOZ looks like and contents of the pack

DAPAGLIFLOZIN SANDOZ film-coated tablets 5 and 10 mg are packed into an aluminium/aluminium foil blister pack.

The blisters are packed together with the leaflet into the cardboard carton.

Pack sizes:

The available pack sizes are 30's and 100's.

Not all pack sizes are marketed

The blister packs are packed into an outer cardboard carton

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd¹

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

This leaflet was last revised in

27 January 2026

Registration numbers

DAPAGLIFLOZIN 5 SANDOZ: 58/21.2/0107.105

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Access to the corresponding Professional Information

Not applicable

¹Company Reg. No.: 1990/001979/07