
Patient Information Leaflet

SCHEDULING STATUS: [S4]

DAPAGLIFLOZIN 5 mg GLENMARK (Film-coated tablet)

DAPAGLIFLOZIN 10 mg GLENMARK (Film-coated tablet)

Dapagliflozin

Contains sugar: lactose anhydrous 28,025 mg and 56,050 mg respectively.

Read all of this leaflet carefully before you start taking DAPAGLIFLOZIN GLENMARK:

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

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

DAPAGLIFLOZIN GLENMARK contains the active substance dapagliflozin and it belongs to a group of medicines called oral hypoglycaemics.

- It is used if your type 2 diabetes cannot be controlled with different medicines for diabetes,

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diet and exercise.

- Your doctor may ask you to take **DAPAGLIFLOZIN GLENMARK** alone or with another diabetes medicine.
- **DAPAGLIFLOZIN GLENMARK** increases the amount of sugar excreted by your kidneys.

DAPAGLIFLOZIN GLENMARK 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 use DAPAGLIFLOZIN GLENMARK

Do not take DAPAGLIFLOZIN GLENMARK:

- if you are allergic to dapagliflozin or any of the other ingredients of this medicine (listed in section 6). If you are not sure, talk to your doctor or pharmacist before taking this medicine.
- If you have moderate or severe kidney disease or if you are on dialysis.
- If you have type 1 diabetes mellitus – the type 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.

Warnings and precautions

Special care should be taken with DAPAGLIFLOZIN GLENMARK:

- 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, trouble breathing,
increased levels of “ketone bodies” in your urine or blood. If this happens to you contact

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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 are on medicines to lower your blood pressure (anti-hypertensives) or water pill (diuretic) and have a history of low blood pressure (hypotension).
- If you often get infections of the urinary tract.
- If you are allergic to any other medicines used to lower the amount of sugar in your blood.
- If you experience pain, tenderness, redness, swelling in your genital area or around your anus, and you have fever and weakness, you should immediately stop taking

DAPAGLIFLOZIN GLENMARK and contact your doctor.

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

Children and adolescents

DAPAGLIFLOZIN GLENMARK has not been studied in children and adolescents, therefore it is not recommended for use in children and adolescents under 18 years of age.

Other medicines and DAPAGLIFLOZIN GLENMARK

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

(This includes all complementary or traditional medicines.)

This is because **DAPAGLIFLOZIN GLENMARK** can affect the way some other medicines work. Also some other medicines can affect the way **DAPAGLIFLOZIN GLENMARK** works.

In particular, tell your doctor or pharmacist before taking **DAPAGLIFLOZIN GLENMARK** if you are taking any of the following medicines:

- ketoconazole (medication for fungal infections)
- water pill (diuretic) – you may be more likely to lose fluid from your body (get

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dehydrated). Your doctor may change your dose.

- Medicines that lower the amount of sugar in your blood – such as insulin or a “sulphonylurea” 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 **DAPAGLIFLOZIN GLENMARK** if you are pregnant or breast-feeding 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 health care provider for advice before taking this medicine.

Driving and using machines

Taking **DAPAGLIFLOZIN GLENMARK** 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 and use any tools or machines, if you feel dizzy while taking **DAPAGLIFLOZIN GLENMARK**.

DAPAGLIFLOZIN GLENMARK contains lactose

DAPAGLIFLOZIN GLENMARK contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. How to use DAPAGLIFLOZIN GLENMARK

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

Always take **DAPAGLIFLOZIN GLENMARK** exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

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The usual dose is one 10 mg tablet each day.

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

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 **DAPAGLIFLOZIN GLENMARK** together with other medicines to lower the amount of sugar in your blood.

Your doctor will tell you how long your treatment with **DAPAGLIFLOZIN GLENMARK** will last. Do not stop treatment early because it may cause a worsening of your condition. If you have the impression that the effect of **DAPAGLIFLOZIN GLENMARK** is too strong or too weak, tell your doctor or pharmacist.

If you take more DAPAGLIFLOZIN GLENMARK than you should

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

If you forget to take DAPAGLIFLOZIN GLENMARK

If you miss a dose of **DAPAGLIFLOZIN GLENMARK**, take it as soon as you remember. If it is close to the time for your next dose, just skip the missed dose. Take the next dose at your regular time.

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

4. Possible side effects

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

DAPAGLIFLOZIN GLENMARK can have side effects.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

This is a very serious side effect. If you have it, you may have had a serious reaction to **DAPAGLIFLOZIN GLENMARK**. 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)
- fast heartbeat

These are signs of losing too much fluid from your body (volume depletion 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 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:

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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 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.

- 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)
- Rash

Less frequent side effects:

- Awakening from sleep at night to pass urine
- Change in amount of creatinine cleared from blood (shown in tests)
- Change in amount of urea in blood (shown in tests).
- Increase thirst and dry feeling of the mouth
- Constipation
- Itching of the genitals
- Increase sweating

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

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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 **DAPAGLIFLOZIN GLENMARK**.

5. How to store DAPAGLIFLOZIN GLENMARK

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package / 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 DAPAGLIFLOZIN GLENMARK contains

- The active ingredient is dapagliflozin.
- The other ingredients are:

Tablet core: anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, sodium stearyl fumarate.

Film-coating material: Polyvinyl alcohol, talc, titanium dioxide, glyceryl monocaprylocaprate, sodium lauryl sulfate, iron oxide yellow.

What DAPAGLIFLOZIN GLENMARK looks like and contents of the pack

DAPAGLIFLOZIN 5 mg GLENMARK: Yellow coloured, round, biconvex, film coated tablets with ‘G’ debossed on one side & ‘81’ debossed on other side.

DAPAGLIFLOZIN 10 mg GLENMARK: Yellow coloured, modified capsule shaped, biconvex, film coated tablets with ‘G’ debossed on one side & ‘482’ debossed on other side.

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DAPAGLIFLOZIN 5 mg and 10 mg GLENMARK are packed in Alu-Alu blister packs of cold forming base foil and peelable lidding foil (8 tablets per blister strip) in pack sizes of 16, 32, or 96.

The blisters are packed in an outer cardboard carton

Holder of Certificate of Registration

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