

Dapagliflozin Devatis

Dapagliflozin 5 mg and 10 mg Film Coated Tablets.

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about DAPAGLIFLOZIN DEVATIS. It does not contain all the information that is known about DAPAGLIFLOZIN DEVATIS.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking DAPAGLIFLOZIN DEVATIS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What DAPAGLIFLOZIN DEVATIS is used for

DAPAGLIFLOZIN DEVATIS is a prescription medicine used with diet, exercise and sometimes other medicines (which may include metformin; insulin; a sulphonylurea medicine such as gliclazide, glimepiride and glibenclamide; or a dipeptidyl peptidase-4 inhibitor [DPP 4 inhibitor] such as sitagliptin or saxagliptin or a glucagon like peptide 1 [GLP-1] receptor agonist such as exenatide) to control the levels of blood sugar (glucose) in patients with Type 2 diabetes mellitus. It can also help prevent hospitalisation for heart failure and kidney disease in patients with type 2 diabetes mellitus.

Type 2 diabetes mellitus

Type 2 diabetes mellitus (also called non-insulin-dependent diabetes mellitus, or NIDDM) is the condition of having high levels of blood sugar (hyperglycaemia). This is usually because your body does not make enough insulin and / or the insulin that your body produces does not work as well as it should. Left uncontrolled, the build-up of high levels of sugar in your blood can lead to serious medical problems.

The main goal of treating type 2 diabetes is to control your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes, which include kidney disease, blindness and amputation.

DAPAGLIFLOZIN DEVATIS is a member of a class of medicines you take by mouth called SGLT-2 (Sodium Glucose Cotransporter-2) inhibitors that lower blood sugar levels in patients with type 2 diabetes mellitus.

DAPAGLIFLOZIN DEVATIS lowers the level of your blood sugar by removing the excess sugar from the body in the urine. DAPAGLIFLOZIN DEVATIS by itself is unlikely to cause low blood sugar (hypoglycaemia) because it does not interfere with the insulin hormone that regulates blood sugar.

Heart failure

Heart failure occurs when the heart is weak and cannot pump enough blood to the lungs and the rest of the body. This can lead to serious medical problems and need for hospital care.

The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling. DAPAGLIFLOZIN DEVATIS helps protect your heart from getting weaker and improves your symptoms. It can lower the need to go to hospital and can help some patients to live longer.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why DAPAGLIFLOZIN DEVATIS has been prescribed for you.

Chronic kidney disease

Chronic kidney disease is the condition when your kidneys gradually lose their function. This means they would not be able to clean and filter your blood the way they should. Loss of kidney function can lead to serious medical problems and need for hospital care.

DAPAGLIFLOZIN DEVATIS helps protect your kidneys from losing their function and can help some patients to live longer.

This medicine is only available with a doctor's prescription.

DAPAGLIFLOZIN DEVATIS is not addictive.

Before you take DAPAGLIFLOZIN DEVATIS

When you must not take it

Do not take DAPAGLIFLOZIN DEVATIS if you have:

- an allergy to dapagliflozin, the active ingredient in DAPAGLIFLOZIN DEVATIS or any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin or you may feel faint.

Do not take DAPAGLIFLOZIN DEVATIS after the use by (expiry) date printed on the pack.

Do not take DAPAGLIFLOZIN DEVATIS if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

DAPAGLIFLOZIN DEVATIS is not recommended for use in children. It has not been studied in children younger than 18 years old.

If you are not sure whether you should start taking DAPAGLIFLOZIN DEVATIS, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have any allergies to:

- any other medicines
- any other substances such as foods, dyes or preservatives

Tell your doctor or pharmacist if you have, or have had, any medical conditions, especially the following:

- type 1 diabetes mellitus
- kidney, liver or pancreas problems

- frequently get genital and urinary tract infections (infections of the bladder, kidney, or tubes that carry urine).
- an illness that will make you dehydrated such as diarrhoea or a severe infection.
- diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood - you may notice this as an unusual fruity odour on your breath, difficulty breathing, confusion and frequent urination).

Tell your doctor if you are pregnant or intend to become pregnant.

The safety of DAPAGLIFLOZIN DEVATIS in pregnant women has not been established. DAPAGLIFLOZIN DEVATIS must not be used during the second and third trimesters of your pregnancy. If you become pregnant, stop taking DAPAGLIFLOZIN DEVATIS and speak with your doctor immediately as good control of your type 2 diabetes (control your blood sugar) is important while you are pregnant as it is not known if DAPAGLIFLOZIN DEVATIS will harm your unborn baby.

Tell your doctor if you are breastfeeding or plan to breastfeed.

DAPAGLIFLOZIN DEVATIS should not be used while breastfeeding or if planning to breastfeed. It is not known if DAPAGLIFLOZIN DEVATIS will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking DAPAGLIFLOZIN DEVATIS.

Tell your doctor if you are lactose intolerant. DAPAGLIFLOZIN DEVATIS tablets contain lactose.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Especially tell your doctor:

- if you are taking a medicine used to remove water from the body (diuretic).
- if you are taking lithium because DAPAGLIFLOZIN DEVATIS can lower the amount of lithium in your blood.

DAPAGLIFLOZIN DEVATIS can be taken with most other medicines.

If you have not told your doctor about any of these things, tell them before you take any DAPAGLIFLOZIN DEVATIS.

How to take DAPAGLIFLOZIN DEVATIS
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Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack ask your doctor or pharmacist for help.

How to take it

Swallow your DAPAGLIFLOZIN DEVATIS tablets with a full glass of water.

How much to take

The dose of DAPAGLIFLOZIN DEVATIS is one 10 mg tablet once a day. You should not take more than one DAPAGLIFLOZIN DEVATIS tablet per day. Your doctor may prescribe DAPAGLIFLOZIN DEVATIS along with certain other medicines.

When to take it

DAPAGLIFLOZIN DEVATIS should be taken once daily at any time of the day regardless of meals. Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

DAPAGLIFLOZIN DEVATIS tablets can be taken with or without food.

How long to take it

Continue taking the tablets for as long as your doctor tells you. Make sure you keep enough DAPAGLIFLOZIN DEVATIS to last over weekends and holidays.

DAPAGLIFLOZIN DEVATIS helps control your condition, but does not cure it. Therefore you must take DAPAGLIFLOZIN DEVATIS every day.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally. Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor or the National Poisons Centre (Ph: 03 474 7000) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much DAPAGLIFLOZIN DEVATIS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking DAPAGLIFLOZIN DEVATIS

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking DAPAGLIFLOZIN DEVATIS. If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking DAPAGLIFLOZIN DEVATIS.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

It is important to have regular check-ups with your doctor or diabetes centre.

HYPOGLYCAEMIA

DAPAGLIFLOZIN DEVATIS does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines, such as insulin or a sulfonylurea.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration

- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.
- If not treated promptly, these may progress to:
- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

HYPERGLYCAEMIA

If you notice the return of any of the signs of hyperglycaemia, contact your doctor immediately.

Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less DAPAGLIFLOZIN DEVATIS than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery).

Your blood glucose may become difficult to control at these times.

If you become pregnant while taking DAPAGLIFLOZIN DEVATIS, tell your doctor immediately.

If you need to have any medical tests while you are taking DAPAGLIFLOZIN DEVATIS, tell your doctor. DAPAGLIFLOZIN DEVATIS may affect the results of some tests.

Visit your doctor regularly for check-ups. Your doctor may want to perform blood tests to check your kidneys, liver, heart, and levels of cholesterol and fats in your blood while you are taking DAPAGLIFLOZIN DEVATIS.

Things you must not do

Do not take DAPAGLIFLOZIN DEVATIS to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how DAPAGLIFLOZIN DEVATIS affects you.

Although rare, DAPAGLIFLOZIN DEVATIS may cause dizziness in some people. Low blood sugar levels may also slow your reaction time and affect your ability to drive or operate machinery.

Make sure you know how you react to DAPAGLIFLOZIN DEVATIS before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking **DAPAGLIFLOZIN DEVATIS**.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment for some side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- hypoglycaemia (see below)
- genital infections as suggested by irritation of the genitals
- urinary tract infections
- back pain
- changes in the amount of cholesterol or fats in your blood
- headache

Low blood sugar (hypoglycaemia) may become worse in people who already take another medication to treat diabetes, such as sulphonylureas or insulin. Tell your doctor if you take other diabetes medicines. If you have symptoms of low blood sugar, you should check your blood sugar and treat if low, then call your doctor. Signs of low blood sugar may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, rapid heartbeat, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers. Do not drive a car if you have signs of low blood sugar.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- Severe allergic reaction (may include shortness of breath, wheezing or severe difficulty in breathing; shock, swelling of the face, lips, tongue or other parts of the body; skin rash, itching or hives on the skin, hayfever, or you may feel faint)
- Genital infections. If you take DAPAGLIFLOZIN DEVATIS, you may be at a greater risk for genital infections. Tell your doctor if you experience painful urination, soreness and more severe irritation or redness and swelling of your genitals, or an unpleasant odour or discharge associated with your genitals.
- Urinary tract infection. If you take DAPAGLIFLOZIN DEVATIS, you may be at a greater risk for urinary tract infections. If you have symptoms, such as burning or pain when you pass urine, more frequent or urgent need to urinate, fever, chills, or blood in the urine, contact your doctor as soon as possible.
- Fournier's gangrene. If you experience pain or tenderness, redness, swelling of the genitals or the area from the genitals to the rectum, fever, and generally feeling unwell. These may be symptoms of a rare but serious and potentially life-threatening infection called Necrotising fasciitis of the perineum (Fournier's gangrene) and you will require prompt treatment.
- Diabetic ketoacidosis. In rare cases dapagliflozin, the active ingredient in DAPAGLIFLOZIN DEVATIS, may cause a serious side effect called diabetic ketoacidosis. Symptoms of diabetic ketoacidosis may include feeling sick or being sick, difficulty breathing, severe thirst, feeling weak and tired, confusion, a sweet smell to your breath, a sweet or metallic taste in your mouth, a strange odour to your urine or sweat and frequent urination. 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.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed here may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking DAPAGLIFLOZIN DEVATIS

Storage

DAPAGLIFLOZIN DEVATIS does not require any special temperature storage conditions. Keep DAPAGLIFLOZIN DEVATIS in a cool dry place. Keep your DAPAGLIFLOZIN DEVATIS tablets in the blister until it is time to take them. If you take DAPAGLIFLOZIN DEVATIS out of the blister it will not keep well.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking DAPAGLIFLOZIN DEVATIS or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What DAPAGLIFLOZIN DEVATIS looks like

DAPAGLIFLOZIN DEVATIS 5 mg Film Coated Tablets are yellow or light yellow, round biconvex film coated tablet debossed with “5” on one side.

DAPAGLIFLOZIN DEVATIS 10 mg Film Coated Tablets are yellow or light yellow, diamond-shaped biconvex film coated tablet debossed with “10” on one side.

DAPAGLIFLOZIN DEVATIS film coated tablets are available in blister packs of 28.

Ingredients

DAPAGLIFLOZIN DEVATIS 5 mg Film Coated Tablets

Each film-coated tablet contains 5 mg of dapagliflozin and the following inactive ingredients: microcrystalline cellulose, lactose anhydrous, croscarmellose sodium, sodium stearyl fumarate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, titanium dioxide, macrogol/PEG, talc, iron yellow oxide.

DAPAGLIFLOZIN DEVATIS 10 mg Film Coated Tablets

Each film-coated tablet contains 10 mg of dapagliflozin and the following inactive ingredients: microcrystalline cellulose, lactose anhydrous, croscarmellose sodium, sodium stearyl fumarate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, titanium dioxide, macrogol/PEG, talc, iron yellow oxide

DAPAGLIFLOZIN DEVATIS film coated tablets do not contain gluten or sucrose.

Marketed by

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