

PACKAGE LEAFLET

Package leaflet: Information for the patient

Ermegisto 100 mg/10 mg film-coated tablets sitagliptin/dapagliflozin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What [Product name] is and what it is used for

What [Product name] is:

[Product name] contains the active substances sitagliptin and dapagliflozin.

Sitagliptin is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lower blood sugar levels in adult patients with type 2 diabetes mellitus.

Dapagliflozin belongs to a group of medicines called “sodium glucose co-transporter-2 (SGLT2) inhibitors”. They work by blocking the SGLT2 protein in your kidney. By blocking this protein, blood sugar (glucose), salt (sodium) and water are removed from your body via the urine.

[Product name] is used for type 2 diabetes:

- in adults aged 18 years and older
- if your type 2 diabetes cannot be controlled with diet and exercise
- if metformin and sitagliptin cannot control your diabetes,
- you are already being treated with sitagliptin and dapagliflozin as single tablets. Your doctor may ask you to switch to this medicine

Diet and exercise can help your body use its blood sugar better. If you have diabetes, it is important to stay on any diet and exercise program recommended by your doctor while taking [Product name].

What is type 2 diabetes and how does [Product name] help?

In type 2 diabetes your body does not make enough insulin or is not able to use the insulin it makes properly. This leads to a high level of sugar in your blood. This can lead to serious problems like heart or kidney disease, blindness, and poor circulation in your arms and legs.

This medicine helps to increase the levels of insulin produced after a meal, decreases the amount of sugar made by the body and removes excess sugar from your body.

Your doctor has prescribed this medicine to help lower your blood sugar, which is too high because of your type 2 diabetes.

2. What you need to know before you take [Product name]

Do not take [Product name]

- if you are allergic to sitagliptin, dapagliflozin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking [Product name] :

- if you have “type 1 diabetes” – the type that usually starts when you are young, and your body does not produce any insulin. [Product name] should not be used to treat this condition.
- if you have or had a disease of the pancreas (such as pancreatitis), or if you have or had gallstones, alcohol dependence or very high levels of triglycerides (a form of fat) in your blood. These medical conditions can increase your chance of getting pancreatitis. Possible signs of pancreatitis are listed in section 4.
- if you have or had a kidney problem
- if you have or had a liver problem
- if you have or had very high levels of sugar in your blood which may make you dehydrated (lose too much body fluid). Possible signs of dehydration are listed in section 4. Tell your doctor before you start taking [Product name] if you have any of these signs.
- if you have or had or develop nausea (feeling sick), vomiting or fever or if you are not able to eat or drink. These conditions can cause dehydration. Your doctor may ask you to stop taking [Product name] until you recover to prevent dehydration.
- if you have or had diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting). Possible signs of diabetic ketoacidosis are listed in section 4.
- if you often get infections of the urinary tract

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking [Product name].

Diabetes and foot care

If you have diabetes, it is important to check your feet regularly and adhere to any other advice regarding foot care given by your health care professional.

Urine glucose

Because of how [Product name] works, your urine will test positive for sugar while you are on this medicine.

Children and adolescents

Do not give this medicine to children under 18 years of age, because [Product name] has not been studied in children.

Other medicines and [Product name]

Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines.

Especially, tell your doctor if you are taking any of the following medicines:

- Medicines used to treat irregular heartbeat and other heart problems (digoxin). The level of digoxin in your blood may need to be checked if taking with [Product name].
- Medicines used to remove water from the body (diuretic).
- Other medicines that lower the amount of sugar in your blood such as insulin or a “sulphonylurea” medicine. Your doctor may want to lower the dose of these other medicines, to prevent you from getting low blood sugar levels (hypoglycaemia).
- medicines to lower your blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension).
- Lithium, used for mental disorders. [Product name] can lower the amount of lithium in your blood.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take this medicine during pregnancy. You should stop taking this medicine if you become pregnant.

You should not take this medicine if you are breast-feeding or plan to breast-feed. It is not known if this medicine passes into breast milk.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported, which may affect your ability to drive or use machines.

Do not drive or use any tools or machines, if you feel dizzy taking [Product name].

Taking this medicine with other medicines called sulphonylureas or with insulin 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.

[Product name] contains lactose and sodium

[Product name] contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

[Product name] contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially “sodium-free”.

3. How to take [Product name]

Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual recommended dose is:

- one [Product name] film-coated tablet. Your doctor will prescribe the strength that is right for you.
- once a day
- swallow the tablet whole with a glass of water, to ensure accurate dosing and avoid unpleasant taste
- you can take your tablet with or without food

Your doctor may prescribe [Product name] alone or with certain other medicines that lower blood sugar. Remember to take these other medicine(s) as your doctor has told you. This will help get the best results for your health.

If you take more [Product name] than you should

If you take more [Product name] tablets than you should, talk to a doctor or go to a hospital immediately.

Take the medicine pack with you.

If you forget to take [Product name]

What to do if you forget to take a tablet.

- If it is 12 hours or more until your next dose, take a dose of [Product name] as soon as you remember.
- Then take your next dose at the usual time.
- If it is less than 12 hours until your next dose, skip the missed dose. Then take your next dose at the usual time.
- Do not take a double dose of [Product name] to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking [Product name] and contact a doctor or the nearest hospital immediately if you notice any of the following serious side effects:

- **Pancreatitis** - severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (frequency not known)
- **Serious allergic reaction (anaphylactic reaction, angioedema)** (very rare). These are signs:
 - swelling of the face, tongue, lips or throat
 - difficulties swallowing and/or breathing
 - hives and breathing problems
 - rash
 - blisters on the skin/peeling skin
- **diabetic ketoacidosis** - this is rare in patients with type 2 diabetes (may affect up to 1 in 1,000 people). These are the signs:
 - increased levels of “ketone bodies” in your urine or blood
 - 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
- rapid weight loss.

This may occur regardless of blood sugar level. Your doctor may decide to temporarily or permanently stop your treatment with [Product name].

- **necrotising fasciitis of the perineum** or Fournier's gangrene, a serious or even life threatening soft tissue infection of the genitals or the area between the genitals and the anus, seen very rarely. These are the signs: 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. Fournier's gangrene has to be treated immediately (very rare).
- **Stevens-Johnson syndrome**, an exfoliative skin condition that usually starts with flu-like symptoms, followed by a painful red or purple rash that spreads and forms blisters on your skin (frequency not known).
- **Bullous pemphigoid**, a type of skin blistering characterized by large, fluid-filled blisters (frequency not known).

Stop taking [Product name] and see a doctor as soon as possible if you notice any of the following serious side effects:

- **urinary tract infection**, seen commonly (may affect up to 1 in 10 people). These are signs of a severe infection of the urinary tract:
 - fever and/or chills
 - burning sensation when passing water (urinating)
 - pain in your back or side.

Although uncommon, if you see blood in your urine, tell your doctor immediately.

Contact your doctor as soon as possible if you have any of the following side effects:

- **low blood sugar levels** (hypoglycaemia), seen very commonly (may affect more than 1 in 10 people) in patients with diabetes taking this medicine with a sulphonylurea or insulin. These are the signs of low blood sugar:
 - 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 levels and what to do if you get any of the signs above.

Other side effects when taking [Product name]:

Common (may affect up to 1 in 10 people)

- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)
- back pain
- passing more water (urine) than usual or needing to pass water more often
- changes in the amount of cholesterol or fats in your blood (shown in tests)
- increases in the amount of red blood cells in your blood (shown in tests)
- decreases in creatinine renal clearance (shown in tests) in the beginning of treatment
- dizziness
- rash
- headache

Uncommon (may affect up to 1 in 100 people)

- loss of too much fluid from your body (dehydration, signs may include very dry or sticky

- mouth, passing little or no urine or fast heartbeat)
- thirst
- constipation
- awakening from sleep at night to pass urine
- dry mouth
- weight decreased
- increases in creatinine (shown in laboratory blood tests) in the beginning of treatment
- increases in urea (shown in laboratory blood tests)
- Fungal infection
- Itching, vulvovaginal itching, genital itching
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Rare (may affect up to 1 in 1000 people)

- Low Blood platelets (Thrombocytopenia)

Very rare (may affect up to 1 in 10 000 people)

- Inflammation of part of the kidneys

Frequency not known

- Scarring of the lungs (Interstitial lung disease)
- Vomiting
 - Hives, itchy skin rash (urticaria)
- Inflammation of the small blood vessels in the skin (cutaneous vasculitis)
 - Joint pain
 - Muscle pain
 - Joint disease or joint problems
 - Kidney problems (sometimes requiring dialysis)
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Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store [Product name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister after “EXP.” The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Product name] contains

The active substances are sitagliptin and dapagliflozin.

- [Product name] 100 mg/10 mg film-coated tablets: each film-coated tablet contains 100 mg sitagliptin (as sitagliptin hydrochloride monohydrate) and 10 mg dapagliflozin (as dapagliflozin amorphous base).

The other ingredients in the tablet core are Cellulose, microcrystalline, Lactose monohydrate, Sodium starch glycolate type A, Magnesium stearate.

The film-coating contains Poly (vinyl) Alcohol– part. Hydrolized, Iron Oxide Yellow, Macrogol, Talc, Iron Oxide Red.

What [Product name] looks like and contents of the pack

[Product name] 100 mg/10 mg film-coated tablet is an light brown, round film-coated tablet with “101” engraved on one side and with diameter 9.9 mm.

Pack sizes

Cartons of 30 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<[To be completed nationally]>

Manufacturer:

<[To be completed nationally]>

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

<[To be completed nationally]>

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