FORTREAS FILM COATED TABLET 100MG

Sitagliptin (as HCl Monohydrate) 100mg

What is in this leaflet

1. What Fortreas is taken for
2. How Fortreas works
3. Before you take Fortreas
4. How to take Fortreas
5. While you are taking it
6. Side effects
7. Storage and Disposal of Fortreas
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What Fortreas is taken for

Fortreas is a tablet that contains 113.38 mg of Sitagliptin HCl monohydrate, which is equivalent to 100 mg, respectively of free base.

- Fortreas helps to improve the levels of insulin after a meal.
- Fortreas decreases the amount of sugar made by the body.
- Fortreas works when blood sugar is high, especially after a meal. This is when the body needs the greatest amount of helps in lowering blood sugar. Fortreas also lowers blood sugar between meals.
- Fortreas by itself is unlikely to cause low blood sugar (hypoglycemia) because is does not work when your blood sugar is low.

How Fortreas works

Fortreas is a member of a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus, or NIDDM.

Why has my doctor prescribed Fortreas?

Your doctor has prescribed Fortreas to help lower your blood sugar, which is too high because of your type 2 diabetes. Fortreas can be used alone or in combination with certain other medicines that lower blood sugar, along with a recommended diet and exercise program.

What is type 2 diabetes?

Type 2 diabetes is a combination in which your body does not make enough insulin and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems.

The main goal of treating diabetes is to lower your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness, and amputation.

High blood sugar can be lowered by diet and exercise, and by certain medicines.

Before you take Fortreas

-When you must not take it

Do not take Fortreas if you are allergic to any of the ingredients in Fortreas.

-Before you start to take it

Tell your doctor if you have or have had:

- Type 1 diabetes
- Diabetic ketoacidosis (increased ketones in the blood or urine)
- Any kidney problems, or any past or present medical problems
- An allergic reaction to Fortreas
- 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.

-Taking other medicines

Fortreas may be taken with most medicines. Tell your doctor about all the medicines you take. This includes prescription and non-prescription medicines and herbal supplements.

In particular, tell your doctor:

- if you are taking digoxin (a medicine used to treat irregular heartbeat and other heart problems). The level of digoxin in your blood may need to be checked if you are taking it with Fortreas.

How to take Fortreas

-How much to take and When to take it

Take Fortreas exactly as your doctor has prescribed. The recommended dose is to take:

- One 100 mg tablet
- Once a day
- By mouth, with or without food

If you have kidney problems, your doctor may prescribe lower doses.

Your doctor may prescribe Fortreas along with certain other medicines that lower blood sugar.

-How long to take it

Continue to take Fortreas as long as your doctor prescribes it so you can continue to help control your blood sugar.

Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor recommended diet, exercise and weight loss program while taking Fortreas.

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-If you forget to use it
If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your nest dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of Fortreas.

-If you use too much (overdose)
If you take more than the prescribed dosage of Fortreas, contact your doctor immediately.

While you are taking it
-Things you must do
Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Fortreas.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do
Do not stop taking the medicine unless advised by your doctor.

Do not give Fortreas to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of
Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving Fortreas. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking Fortreas and call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

Cases of a skin reaction called bullous pemphigoid that can require treatment in a hospital have been reported in patients receiving Fortreas. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking Fortreas.

Use in children
Fortreas is not effective in children and adolescent 10 to 17 years of age with type 2 diabetes.

Fortreas has not been studied in children younger than 10 years of age.

Use in the elderly
In studies, Fortreas worked well in and was well-tolerated by older adult patients. No dosage adjustment is necessary based on age.

Use in pregnancy and breast-feeding
Women who are pregnant or plan to become pregnant should consult with their doctor before taking Fortreas. Fortreas is not recommended for use during pregnancy.

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

Can I drive or operate machinery while using Fortreas?
There is no information to suggest that Fortreas affects your ability to drive a car or operate machinery.

Side effects
Like all prescription medicines, Fortreas may cause side effects. In studies, side effects usually were mild and did not cause patients to stop taking Fortreas. The side effects reported in patients treated with Fortreas were similar to side effects in patients treated with a tablet containing no medication (a placebo).

When Fortreas is used in combination with a sulfonylurea medicine or with insulin, low blood sugar with symptoms (hypoglycemia) due to the sulfonylurea or insulin can occur. Lower doses of the sulfonylurea medicine or insulin may be required.

When Fortreas was used in combination with insulin, the following additional side effects were reported:

- Flu
- Headache

When Fortreas and metformin were started together, the following side effects were reported:

- Diarrhea
- Indigestion
- Flatulence
- Vomiting
- Headache

When Fortreas and pioglitazone were started together, the side effect of decreased blood sugar measurements without symptoms of hypoglycemia was reported.

When Fortreas was used in combination with metformin and rosiglitazone, the following side effects were reported:

- Headache
- Low blood sugar with symptoms (hypoglycemia)
- Diarrhea
- Upper respiratory infection
- Nausea
- Cough
- Fungal skin infection
- Swelling of the hands or legs
- Vomiting

Additional side effects have been reported in general use with Fortreas, by itself and/or with other diabetes medicines:

- Allergic reactions, which may be serious, including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. If you have an allergic reaction, stop taking Fortreas and call your doctor right away. Your doctor may prescribe a medication for your allergic reaction and a different medication for your diabetes.
- Inflammation of the pancreas.
- Kidney problems (sometimes requiring dialysis).
- Upper respiratory infection.
- Stuffy or runny nose and sore throat.

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- Constipation.
- Vomiting.
- Headache.
- Joint pain.
- Muscle aches.
- Arm or leg pain.
- Back pain.
- Itching.
- Blisters.
- Reduced number of platelets.

Tell your doctor or pharmacist if you develop any unusual side effect, or if any known side effect does not go away or gets worse.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

How can I learn more about Fortreas and diabetes?
You may obtain further information from your doctor or pharmacist, who has more detailed information.

Storage and disposal of Fortreas

-Storage
Store in a dry place 30ºC.
Protect from light.

Keep out of reach of children.

-Disposal
How long should I keep my medicines?
Do not use this medicine after month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

Product description
-What it looks like
Yellow, round, biconvex, film coated tablet with "100" on one side and scored on the other. Tablet can be split to half when necessary.

-Ingredients
Sitagliptin Hydrochloride Monohydrate

-Inactive Ingredients
Polyvinylpyrrolidone
Microcrystalline Cellulose
Dibasic Calcium Phosphate
Croscarmellose Sodium
Magnesium Stearate
Opadry II Yellow
Purified Water

-MAL Number

Manufacturer
Duopharma Manufacturing (Bangi) Sdn. Bhd.
Lot No. 2&4, Jalan P/7, Section 13,
Bangi Industrial Estate, 43650,
Bandar Baru Bangi, Selangor,
Malaysia.

Product Registration Holder
Duopharma Manufacturing (Bangi) Sdn. Bhd.
Lot No. 2, 4, 6, 8 & 10,
Jalan P/7, Section 13,
Bangi Industrial Estate, 43650,
Bandar Baru Bangi, Selangor,
Malaysia.

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