

Trevia™

[SITAGLIPTIN TABLETS USP]

50mg, 100mg Tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

WHAT IS IN THIS LEAFLET

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WHAT TREVIA IS AND WHAT IT IS USED FOR

TREVIA contains the active substance sitagliptin which is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus, or NIDDM.

This medicine helps to improve the levels of insulin after a meal and decreases the amount of sugar made by the body.

BEFORE YOU USE TREVIA

When you must not use TREVIA

- If you allergic to the active substance sitagliptin or any of the other ingredients of this medicine.
- If you have Type 1 diabetes or have increased ketones in the blood or urine.
- If you are under 18 years of age.

Before you start to use TREVIA

To make sure TREVIA is safe for you, tell your doctor:

- If you have had inflammation of your pancreas (pancreatitis).
- If you have kidney problems.
- If you have any medical conditions.
- If you are pregnant or plan to become pregnant.

Taking other medicines

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

Your doctor may prescribe this medicine alone or with certain other medicines that lower blood sugar.

HOW TO USE TREVIA

How much to use

Use TREVIA exactly as directed by your doctor. Follow all directions on your prescription label. The usual dose is one 100mg film-coated tablet once a day by mouth. You may take TREVIA with or without food.

When to use it

TREVIA is used along with diet and exercise to lower blood sugar in adults with Type 2 diabetes. It can be taken alone or along with certain other medicines to control blood sugar level.

How long to use it

Continue to take this medicine as long as your doctor prescribes it so you can continue to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first.

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

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 next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of this medicine.

If you are unsure about what to do ask your doctor or pharmacist.

If you use too much (overdose)

If you take more than the prescribed dosage, contact your doctor immediately.

WHILE YOU ARE USING IT

Thing you must do

- The amount of diabetes medicine may change when your body is under some type of stress, such as fever, trauma (such as car accident), infection or surgery. Tell your doctor immediately if you have any of these conditions and follow your doctor's instructions.
- Check your blood sugar as your doctor tells you to.
- Stay on your prescribed diet and exercise program while taking TREVIA.
- Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia) and problems you have because of your diabetes.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.

Thing you must not do

Stop taking TREVIA and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be the symptoms of pancreatitis.

Thing to be careful of pregnancy, breast-feeding and fertility

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.

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

Driving and using machines

This medicine has no known 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.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycemia, which may affect your ability to drive and use machines or work without safe foothold.

POSSIBLE SIDE EFFECTS

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

Side effects while taking sitagliptin alone:

Upper respiratory tract infections, headache, stuffy or runny nose and sore throat.

Side effects after adding sitagliptin to metformin:

Common: Nausea

Uncommon: Drowsiness, stomach discomfort (diarrhea and upper abdominal pain) and low blood sugar.

Side effects while taking sitagliptin in combination with a sulphonylurea:

Common: low blood sugar.

Side effects while taking sitagliptin and pioglitazone:

Common: low blood sugar and flatulence, foot swelling (edema).

Side effects while taking sitagliptin in combination with a sulphonylurea and metformin:

Very common: Low blood sugar.

Common: Constipation.

Side effects while taking sitagliptin in combination with rosiglitazone and metformin:

Common: Low blood sugar, headache, diarrhea, vomiting and foot swelling (edema).

Side effects while taking sitagliptin in combination with insulin:

Common: Flu, low blood sugar and headache.

Uncommon: Dry mouth, constipation.

HOW TO STORE TREVIA

Storage:

Do not store above 30°C.

Protect from sunlight and moisture.

Keep out of reach of children.

How to check the expiry date of medicine

Do not use this medicine after the expiry date stated on the blister and carton. The expiry date refers to the last day of the month.

Disposal

Do not throw away any medicine via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use.

FURTHER INFORMATION

Product Description:

What TREVIA looks like:

TREVIA Tablets 50mg is peach orange colored, round shaped biconvex, film-coated tablet, plain on both sides.

TREVIA Tablets 100mg is peach orange colored, round shaped biconvex, film-coated tablet, bisect line on one side and plain on the other side.

Ingredient:

Active ingredient:

Sitagliptin.

Each film-coated tablet contains: Sitagliptin phosphate (as monohydrate) USP equivalent to Sitagliptin...50mg

Each film-coated tablet contains: Sitagliptin phosphate (as monohydrate) USP equivalent to Sitagliptin...100mg

In-active Ingredients:

Anhydrous Dibasic Calcium Phosphate, Microcrystalline Cellulose (Avice PH 102), Croscarmellose Sodium, Hypromellose (Pharmacoat 606), Colloidal Anhydrous Silica (Aerosil 200), Magnesium Stearate and Sodium Stearyl Fumarate.

Film-coating materials:

Hypromellose (HPMC 5CPS), Macrogols (PEG 6000), Instacoat Brown and Titanium Dioxide.

DATE OF PREPARATION

August 28, 2015



MANUFACTURER AND PRODUCT REGISTRATION HOLDER:

Getz Pharma (Pvt.) Ltd. 29-30/27, Korangi Industrial Area,
Karachi - 74900, Pakistan.

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