Zyglip Film Coated Tablet

Sitagliptin (50mg, 100mg)

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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 Zyglip is used for

Zyglip is a tablet that contains 50, or 100 mg of sitagliptin as the active ingredient.

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

How Zyglip works

Zyglip 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 Zyglip?

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

- *When you must not use it*

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

- *Before you start to use 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 Zyglip
- 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*

Zyglip 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 heart beat and other heart problems). The level of digoxin in your blood may need to be checked if you are taking it with Zyglip.

How to use Zyglip

- *How much to use and When to take it*

Take Zyglip 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 Zyglip along with certain other medicines that lower blood sugar.

- *How long to use it*

Continue to take Zyglip for as long as your doctor prescribes

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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 Zyglip.

- *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 Zyglip.

- *If you use too much (overdose)*

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

While you are using 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 Zyglip.

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 start taking any new medication without discussing it with your doctor or pharmacist.

Do not give Zyglip 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 Zyglip. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking Zyglip 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 Zyglip. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking Zyglip.

Use in children

Zyglip is not effective in children and adolescents 10 to 17 years of age with type 2 diabetes. Zyglip has not been studied in children younger than 10 years of age.

Use in the elderly

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

Use in pregnancy and breastfeeding

Women who are pregnant or plan to become pregnant should consult with their doctor before taking Zyglip. Zyglip is not recommended for use during pregnancy.

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

Can I drive or operate machinery while using Zyglip?

There is no information to suggest that Zyglip affects your ability to drive a car or operate machinery.

Side effects

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

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

- Flu
- Headache

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

- Diarrhea
- Indigestion
- Flatulence
- Vomiting
- Headache

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

When Zyglip 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 Zyglip, by itself and/or with other diabetes medicines:

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- 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 Zyglip and call your doctor right away. Your doctor may prescribe a medication to treat 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.
- 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 or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Zyglip

- *Storage*

Store below 30ºC.

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 pack after "EXP". The expiry date refers to the last day of the month.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Zyglip Film Coated Tablet 50mg
Pink, round, biconvex, film-coated tablets debossed with "SN" on one side and "50" on the other side.

Zyglip Film Coated Tablet 100mg
Brown, round, biconvex, filmcoated tablets debossed with "SN" on one side and "100" on the other side.

- *Ingredients*
  - Active ingredient:

Sitagliptin phosphate

  - Inactive ingredients

Excipients**:**
Calcium Hydrogen Phosphate Anhydrous
Microcrystalline cellulose
Croscarmellose sodium
Low-Substituted Hydroxypropyl Cellulose
Colloidal Silicon Dioxide
Magnesium stearate
Sodium stearyl fumarate

Film coating
Hydroxypropylmethyl cellulose
Hydroxypropylcellulose
Polyethylene glycol
Titanium dioxide
Ferric oxide, yellow
Ferric oxide, red
Ferric oxide, black (100mg)
Talc

MAL Number

Zyglip Film Coated Tablet 50mg
MALxxxxxxxxAZ

Zyglip Film Coated Tablet 100mg
MALxxxxxxxxAZ

Manufacturer
Sandoz Private Limited
Plot No. 8-A/2 and 8-B, TTC Industrial Area, Kalwe Block, Village Dighe, Thane, 400708, India.

Product Registration Holder
Sandoz Products Malaysia Sdn. Bhd.
3A-2 & 3A-3, Level 3A, Menara KEN TTDI,
No. 37, Jalan Burhanuddin Helmi, Taman Tun Dr Ismail,
60000 Kuala Lumpur, Malaysia.

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