

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Pansiptin 100 Tablets Sitagliptin 100 mg film coated 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 health care provider.
- 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

- a) What Pansiptin is and what it is used for
- b) Before you take Pansiptin
- c) How to take Pansiptin
- d) Possible side effects
- e) How to store Pansiptin
- f) Further information

a) WHAT PANSIPTIN IS AND WHAT IT IS USED FOR

Pansiptin film-coated tablet 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.

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

Your doctor has prescribed this medicine to help lower your blood sugar, which is too high because of your type 2 diabetes. This medicine can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or glitazones) that lower blood sugar, which you may already be taking for your diabetes together with a food and exercise plan.

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 like heart disease, kidney disease, blindness, and amputation.

b) BEFORE YOU TAKE PANSIPTIN

Do not take Pansiptin

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

Take special care with Pansiptin

- Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving sitagliptin (see section 4).

If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop Pansiptin.

Tell your doctor if you have or have had:

- a disease of the pancreas (such as pancreatitis)
- 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 (see section 4)

- type 1 diabetes
- diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting)
- any past or present kidney problems
- an allergic reaction to sitagliptin (see section 4).

This medicine is unlikely to cause low blood sugar because it does not work when your blood sugar is low. However, when this medicine is used in combination with a sulphonylurea medicine or with insulin, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your sulphonylurea or insulin medicine.

Children and adolescents

Children and adolescents below 18 years should not use this medicine. It is not effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years.

Taking other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 taking with Pansiptin.

Taking Pansiptin with food and drink

You can take this medicine with or without food and drink

Pregnancy and breast-feeding

Ask your health care provider for advice before taking any medicine.

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 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.

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

c) **HOW TO TAKE PANSIPTIN**

Always take Pansiptin exactly as your health care provider has told you. You should check with your health care provider if you are not sure.

The usual recommended dose is:

- one 100 mg film-coated tablet
- once a day
- by mouth

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

If you have kidney problems, your doctor may prescribe lower doses (such as 25 mg or 50 mg). You can take this medicine with or without food and drink.

Your doctor may prescribe this medicine alone or with certain other medicines that lower blood sugar. Diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise recommended by your doctor while taking Pansiptin.

If you take more Pansiptin than you should

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

If you forget to take Pansiptin

Do not take a double dose to make up for a forgotten dose.

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.

If you stop taking Pansiptin

If you have any further questions on the use of this product, ask your health care provider.

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.

d) **POSSIBLE SIDE EFFECTS**

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

STOP taking Pansiptin and contact a doctor immediately if you notice any of the following serious side effects:

- 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 (pancreatitis).

If you have a serious allergic reaction (frequency not known), including rash, hives, blisters on the skin/peeling skin and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, stop taking this medicine and call your doctor right away.

Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Some patients have experienced the following side effects after adding sitagliptin to metformin:

Common (may affect up to 1 in 10 people): low blood sugar, nausea, flatulence, vomiting

Uncommon (may affect up to 1 in 100 people): stomach ache, diarrhoea, constipation, drowsiness

Some patients have experienced different types of stomach discomfort when starting the combination of sitagliptin and metformin together (frequency is common).

Some patients have experienced the following side effects while taking sitagliptin in combination with a sulphonylurea and metformin:

Very common (may affect more than 1 in 10 people): low blood sugar

Common: constipation

Some patients have experienced the following side effects while taking sitagliptin and pioglitazone:

Common: flatulence, swelling of the hands or legs

Some patients have experienced the following side effects while taking sitagliptin in combination with pioglitazone and metformin:

Common: swelling of the hands or legs

Some patients have experienced the following side effects while taking sitagliptin in combination with insulin (with or without metformin):

Common: flu

Uncommon: dry mouth

Some patients have experienced the following side effects while taking sitagliptin alone in clinical studies, or during post-approval use alone and/or with other diabetes medicines:

Common: low blood sugar, headache, upper respiratory infection, stuffy or runny nose and sore throat, osteoarthritis, arm or leg pain

Uncommon: dizziness, constipation, itching

Rare: reduced number of platelets

Frequency not known: kidney problems (sometimes requiring dialysis), vomiting, joint pain, muscle pain, back pain, interstitial lung disease, bullous pemphigoid (a type of skin blister)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

e) **HOW TO STORE PANSIPTIN**

Keep out of the reach and sight of children.

Do not store above 30°C, Store in the original pack.

Do not use Pansiptin after the expiry date. The expiry date refers to the last day of that month.

Do not use Pansiptin if you notice visible signs of deterioration.
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.

f) FURTHER INFORMATION

What Pansiptin contains:

The active pharmaceutical ingredient in Pansiptin 100 is Sitagliptin.
Each film coated tablet contains Sitagliptin hydrochloride monohydrate equivalent to Sitagliptin 100 mg.

The other ingredients are

Table core: Calcium phosphate dibasic anhydrous, microcrystalline cellulose (E460), croscarmellose sodium (E468), silica colloidal anhydrous, sodium stearyl fumarate, magnesium stearate (E470b)

Film coating: Polyvinyl alcohol partially hydrolyzed (E1203), titanium dioxide (E171), macrogol/PEG (E1521), talc (E553b), iron oxide yellow (E172), iron oxide red (E172).

What Pansiptin looks like and contents of the pack:

Round, beige film-coated tablet.

Blisters (PVC/PE/PVDC and aluminium) in 15's, 14's, 10's pack.

Not all packs are marketed.

Manufacturer for:

MEGA LIFESCIENCES (AUSTRALIA) PTY LTD
Victoria 3810, Australia.

Manufactured by:

SAG MANUFACTURING, S.L.U
Ctra. N-I, Km 36, San Agustin de Guadalix, 28750
Madrid, Spain.

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