PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

METPLITIN 25 mg

METPLITIN 50 mg

METPLITIN 100 mg

Film-coated tablet

Sitagliptin

Sugar free

Read all of this leaflet carefully before you start taking METPLITIN

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- METPLITIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What METPLITIN is and what it is used for

METPLITIN contains sitagliptin hydrochloride.

Sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). It lowers blood sugar levels in adult patients with a form of diabetes called "Type 2 diabetes mellitus". Type 2 diabetes is also called non-insulin-dependent diabetes mellitus or NIDDM.

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

Along with diet and exercise, METPLITIN helps lower your blood sugar. METPLITIN can be used alone or with certain other medicines for diabetes (metformin or glitazones).

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.

2. What you need to know before you take METPLITIN

Do not take METPLITIN if you:

- are allergic (hypersensitive) to sitagliptin or any of the other ingredients of METPLITIN (see "What METPLITIN contains").
- if you have a history of serious allergic reactions to sitagliptin or other gliptins.
- if you have severe liver problems.

Warnings and precautions

Special care should be taken with METPLITIN.

Before you start taking METPLITIN, tell your doctor if you suffer from any of the following:

- if you have pancreas problems. Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving METPLITIN (see section 4).
- if you have or have had an allergic reaction to sitagliptin, or METPLITIN (see section 4).
- if you are taking a sulphonylurea or insulin, diabetes medicines, together with METPLITIN, as you may experience low blood sugar levels (hypoglycaemia). Your doctor may reduce the dose of your sulphonylurea or insulin.
- if you have kidney problems.
- if you have skin problems.
- 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 METPLITIN.
- Type 1 diabetes. METPLITIN should not be used to treat Type 1 diabetes.
- diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting).

Children and adolescents

METPLITIN should not be used in children under 18 years of age.

Other medicines and METPLITIN

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Taking METPLITIN with some medicines may mean the doctor will need to change your dose of METPLITIN or the other medicines.

Tell your doctor if you are taking the following:

- 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 METPLITIN.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking METPLITIN.

METPLITIN may cause harm to your unborn child if you are taking it while being pregnant. You should not use METPLITIN if you are pregnant.

You should not take METPLITIN if you are breastfeeding.

Driving and using machines

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

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 (low blood sugar), which may affect your ability to drive and use machines or work without safe foothold.

It is not always possible to predict to what extent METPLITIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which METPLITIN affects them.

3. How to take METPLITIN

Do not share medicines prescribed for you with any other person.

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

Do not change the dose or stop taking METPLITIN without talking with your doctor or pharmacist.

Talk with your doctor about how long you should keep on taking METPLITIN.

METPLITIN is for oral use.

You should swallow your tablet whole with a glass of water.

The recommended dose to take is:

One 100 mg tablet once a day by mouth, with or without food.

If you have reduced kidney function, your doctor may prescribe a lower dose.

You should continue the diet recommended by your doctor during treatment with this medicine and take care that your carbohydrate intake is equally distributed over the day.

If you have the impression that the effect of METPLITIN is too strong or too weak, talk to your doctor or pharmacist.

If you take more METPLITIN than you should

If you take more than the prescribed dosage of this medicine, contact your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take METPLITIN

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 METPLITIN.

If you stop taking METPLITIN

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 stop taking METPLITIN, your blood sugar may rise again.

If you have any further questions on the use of this product, ask your doctor, pharmacist or other healthcare provider.

4. Possible side effects

METPLITIN can have side effects.

Not all side effects reported for METPLITIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking METPLITIN, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking METPLITIN and tell your doctor, pharmacist or healthcare provider immediately or go to the casualty department at your nearest hospital:

- 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, throat tightness, shortness of breath and wheezing.
- allergic reactions, including death, can happen in patients taking METPLITIN even after only one dose.
- 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).

These are all very serious side effects. If you have them, you may have had a serious allergic

reaction to METPLITIN. You may need urgent medical attention or hospitalisation.

Tell your doctor, pharmacist or healthcare provider if you notice any of the following:

Frequent side effects:

- low blood sugar levels – you may experience a fast heartbeat, shaking, sweating, feeling nervous or anxious, irritable or confused.
- headache.

Less frequent:

- decrease in platelets which causes nosebleeds, bleeding gums, blood in urine, heavy menstrual periods, and bruising.
- dizziness.
- hard stools (constipation).
- itching.

Side effects with unknown frequencies:

- lung disease – you may experience shortness of breath, dry, hacking cough, extreme tiredness and weakness.
- throwing up (vomiting).
- swelling, rash, hives, skin problems.
- joint, muscle, back pain.
- kidney problems – you may notice a decrease in passing urine, swelling of legs and ankles, shortness of breath.

If you notice any other side effects not on this leaflet, please inform your doctor, pharmacist or other healthcare provider.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or health care professional. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of METPLITIN.

5. How to store METPLITIN

Store at or below 25 °C.

Keep the tablets in the blisters and the blisters in the outer carton until required for use.

Keep all medicines out of reach and sight of children.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

Do not store in bathrooms.

Do not use after the expiry date stated on the carton/blister.

6. Contents of the pack and other information

What METPLITIN contains

The active substance is sitagliptin.

METPLITIN 25 mg: Each tablet contains sitagliptin hydrochloride monohydrate, equivalent to 25 mg sitagliptin.

METPLITIN 50 mg: Each tablet contains sitagliptin hydrochloride monohydrate, equivalent to 50 mg sitagliptin.

METPLITIN 100 mg: Each tablet contains sitagliptin hydrochloride monohydrate, equivalent to 100 mg sitagliptin.

The other ingredients for the tablets core are: calcium hydrogen phosphate, croscarmellose sodium,

magnesium stearate, microcrystalline cellulose, povidone (K-30), purified water.

The other ingredients for the film-coating are: iron oxide yellow (METPLITIN 50 mg & 100 mg), iron oxide red (METPLITIN 100 mg), macrogol (3350)/PEG, polyvinyl alcohol-part, hydrolysed, titanium dioxide, talc.

What METPLITIN looks like and contents of the pack

METPLITIN 25 mg: White coloured, round shaped tablets (Diameter: approximately 6 mm) debossed with "411" on one side and plain on the other side.

METPLITIN 50 mg: Yellow coloured round shaped tablets (Diameter: approximately 8 mm) debossed with "417" on one side and plain on the other side.

METPLITIN 100 mg: Brown coloured, round shaped tablets (Diameter: approximately 10 mm) debossed with "471" on one side and plain on the other side.

METPLITIN are packed in OPA/Alu/PVC-Alu cold formable foil and hard tempered aluminium foil with heat seal lacquer coating or clear PVC (polyvinyl chloride) foil laminated with aclar and hard tempered aluminium foil with heat seal lacquer coating: blister packs of 28, 30, 56, 60 tablets with blisters containing 7, 10 or 14 tablets.

Not all pack sizes may be marketed.

Holder of the Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

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This leaflet was last revised in

28 May 2024

Registration numbers

METPLITIN 25 mg: 56/21.2/0996

METPLITIN 50 mg: 56/21.2/0997

METPLITIN 100 mg: 56/21.2/0998

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration: Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories web site:

http://www.drreddys.co.za