Dr. Reddy's Laboratories (Pty) Ltd.
METPLITIN CO 50/850; 50/1 000
APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

METPLITIN CO 50/850

METPLITIN CO 50/1 000

Sitagliptin hydrochloride monohydrate / Metformin hydrochloride

Film-coated tablet

Sugar free

Read all of this leaflet carefully before you start taking METPLITIN CO tablets

- 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 CO 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 CO is and what it is used for

2. What you need to know before you take METPLITIN CO

3. How to take METPLITIN CO

4. Possible side effects

5. How to store METPLITIN CO

6. Contents of the pack and other information

1. What METPLITIN CO is and what it is used for

METPLITIN CO contains two different prescription medicines, sitagliptin hydrochloride monohydrate and metformin hydrochloride.

- Sitagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors).
- Metformin belongs to a class called biguanides.

They work together to control 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 CO helps lower your blood sugar. METPLITIN CO can be used alone or with certain other medicines for diabetes (sulphonylureas).

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 CO

Do not take METPLITIN CO if you:

- are allergic (hypersensitive) to sitagliptin or metformin or any of the other ingredients of METPLITIN CO (see "What METPLITIN CO contains").
- have severely reduced kidney function.
- have uncontrolled diabetes, with e.g., high blood glucose, nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- have a severe infection or are dehydrated.
- are going to have an X-ray where you will be injected with a dye. You will need to stop taking

METPLITIN CO at the time of the X-ray and for 2 or more days after as directed by your doctor, depending on how your kidneys are working.
• have recently had a heart attack or have severe circulatory problems, such as 'shock' or breathing difficulties.
• have liver problems.
• drink alcohol to excess (either every day or only from time to time).
• are breast-feeding.
Warnings and precautions
Special care should be taken with METPLITIN CO:
Before you start taking METPLITIN CO, 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 CO (see section 4).
• if you have or have had an allergic reaction to sitagliptin, metformin, or METPLITIN CO (see section 4).
• if you are elderly.
• if you are taking a sulphonylurea, diabetes medicines, together with METPLITIN CO, as you may experience low blood sugar levels (hypoglycaemia). Your doctor may reduce the dose of your sulphonylurea or insulin.
• 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 CO.
• Risk of lactic acidosis: METPLITIN CO may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).

If any of the above apply to you, talk to your doctor for further instructions.

- stop taking METPLITIN CO for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

- stop taking METPLITIN CO and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- ✓ vomiting
- ✓ stomach ache (abdominal pain)
- ✓ muscle cramps
- ✓ a general feeling of not being well with severe tiredness
- ✓ difficulty in breathing
- ✓ reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

- if you have high blood sugar (characterised by symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite and feeling weak), or a family history of diabetes.

- if you need to have major surgery you must stop taking METPLITIN CO during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with METPLITIN CO.

- during treatment with METPLITIN CO your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

Children and adolescents

Children and adolescents below 18 years should not use this medicine.

Use in the elderly

METPLITIN CO should be used with caution as age increases. Care should be taken in dose selection and should be based on careful and regular monitoring of kidney function.

Other medicines and METPLITIN CO

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

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

Tell your doctor if you are taking the following:

- medicines (taken by mouth, inhalation, or injection) used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids).
- medicines which increase urine production (diuretics).
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- specific medicines for the treatment of bronchial asthma (β-sympathomimetics).
- iodinated contrast agents or alcohol-containing medicines.
- certain medicines used to treat stomach problems such as cimetidine.
- ranolazine, a medicine used to treat angina.
- dolutegravir, a medicine used to treat HIV infection.
- vandetanib, a medicine used to treat a specific type of thyroid cancer (medullary thyroid cancer).
- digoxin (to treat irregular heartbeat and other heart problems). The level of digoxin in your blood may need to be checked if taking with METPLITIN CO.

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example, in the context of an X-ray or scan, you must stop taking METPLITIN CO before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with METPLITIN CO.

These medicines may increase the risk of side effects or reduce the effect of METPLITIN CO; if you get any

unusual symptom taking any of these medicines together with METPLITIN CO you should see your doctor or healthcare provider.

METPLITIN CO with food and drink

Avoid excessive alcohol intake while taking METPLITIN CO since this may increase the risk of lactic acidosis (see section "Warnings and precautions").

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 CO.

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

You should not take METPLITIN CO if you are breastfeeding.

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 with sitagliptin, 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.

3. How to take METPLITIN CO

Do not share medicines prescribed for you with any other person.
Always take METPLITIN CO 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 CO without talking with your doctor or pharmacist.
Talk with your doctor about how long you should keep on taking METPLITIN CO.

METPLITIN CO is for oral use.

You should swallow your tablet whole with a glass of water.
METPLITIN CO can be taken with food.

Take the dose prescribed to you by your doctor twice daily, with meals.

Your doctor may need to increase your dose to control your blood sugar.

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.

METPLITIN CO alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When this medicine is used with a sulphonylurea medicine, low blood sugar can occur and your doctor may reduce the dose of your sulphonylurea or insulin.

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

If you take more METPLITIN CO than you should

If you take more than the prescribed dosage of this medicine, contact your doctor immediately. Go to the hospital if you have symptoms of lactic acidosis such as feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, unexplained weight loss, muscular cramps, or rapid breathing (see section "Warnings and precautions").

If you forget to take METPLITIN CO

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 stop taking METPLITIN CO

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 CO, 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 CO can have side effects.

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

If any of the following happens, stop taking METPLITIN CO 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 CO 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).
- METPLITIN CO may cause a very rare, but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens, you must stop taking METPLITIN CO and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to METPLITIN CO. 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.
- feeling sick (nausea), throwing up (vomiting), passing gas (flatulence).

Less frequent

- decrease in platelets which causes nosebleeds, bleeding gums, blood in urine, heavy menstrual periods, and bruising.
- feeling sleepy.

- loose stools (diarrhoea), hard stools (constipation), stomach pain.
- itching.

Side effects with unknown frequencies

- allergic reactions.
- lung disease.
- inflammation of the pancreas.
- swelling, rash, hives.
- joint, muscle, back and leg and arm pains.
- kidney problems.

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 Co.

5. How to store METPLITIN CO

Store at or below 25 °C.

Protect from light and moisture.

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 CO contains

The active substances are sitagliptin hydrochloride monohydrate and metformin hydrochloride.

METPLITIN CO 50/850: Each tablet contains 50 mg sitagliptin hydrochloride monohydrate and 850 mg metformin hydrochloride.

METPLITIN CO 50/1 000: Each tablet contains 50 mg sitagliptin hydrochloride monohydrate and 1000 mg metformin hydrochloride.

The other ingredients of the tablet core are magnesium stearate, microcrystalline cellulose, povidone (PVP K30), purified water, sodium lauryl sulphate.

The other ingredients of the film-coating are iron oxide red, iron oxide yellow, macrogol/PEG, Polyvinyl alcohol-part, hydrolysed, talc, titanium dioxide.

What METPLITIN CO looks like and contents of the pack

METPLITIN CO 50/850: White coloured, bi-convex, oval tablets with "I" debossed on one side and plain on the other side.

METPLITIN CO 50/1 000: Brown colored, biconvex, oval tablets with "7" debossed on one side and plain on other side.

METPLITIN CO tablets are packed in OPA/Alu/PVC-Alu blisters in packs of 30 or 60 tablets with blisters containing 10 tablets.

Not all strengths and pack sizes may be marketed.

This leaflet was last revised in

01 October 2024

Registration number

METPLITIN CO 50/850: 56/21.2/0994

METPLITIN CO 50/1 000: 56/21.2/0995

Dr. Reddy's Laboratories (Pty) Ltd.
METPLITIN CO 50/850; 50/1 000
APPROVED PATIENT INFORMATION LEAFLET

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