SCHEDULING STATUS

S3

METFORMIN 500 mg PHARMC, film-coated tablets

METFORMIN 850 mg PHARMC, film-coated tablets

METFORMIN 1000 mg PHARMC, film-coated tablets

Metformin hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking METFORMIN PHARMC

- Keep this leaflet. You may need to read it again.
- If you have more questions, please ask your doctor or your pharmacist.
- METFORMIN PHARMChas been prescribed for you personally and you should not share it with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What METFORMIN PHARMCis and what it is used for

METFORMIN PHARMC contains metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides.

METFORMIN PHARMC is used to treat patients with type 2 diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients.

Adults can take METFORMIN PHARMC on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).

Children 12 years and over and adolescents can take METFORMIN PHARMC on its own or together with insulin.

2. What you need to know before you take METFORMIN PHARMC

Do not take METFORMIN PHARMC:

- If you are hypersensitive (allergic) to metformin hydrochloride or any of the other ingredients of METFORMIN PHARMC (listed in section 6).
- If you have severe complications of your diabetes such as diabetic ketoacidosis, a metabolic state resulting from a profound lack of insulin.
- If your kidneys do not work properly or do not work at all.
- If you have a short term conditions that may affect your kidney function e.g. dehydration, severe infection, shock.
- administration of iodinated contrast media through the veins.
- If you have short or long term conditions that may cause a lack of oxygen to your tissues such as heart or breathing failure, a recent heart attack, shock.
- If you suffer from a liver condition, or use excessive amounts of alcohol.
- If you have or have a history of inflammation of your pancreas.
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special care with METFORMIN PHARMC if you have the following:

Risk of lactic acidosis

METFORMIN PHARMC 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 METFORMIN PHARMC 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 lessfluid than normal. Talk to your doctor for further instructions.

Stop taking METFORMIN PHARMC 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 need to have major surgery, you must stop taking METFORMIN PHARMC during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with METFORMIN PHARMC.

METFORMIN PHARMC on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take METFORMIN PHARMC together with other medicines to treat

diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, vision disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

During treatment with METFORMIN PHARMC, 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.

The use of METFORMIN PHARMC may cause reduction in your levels of vitamin B12. Your doctor will check your levels of B12 at least once a year.

Other precautions:

- All patients should continue their diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.
- The usual laboratory tests for diabetes monitoring should be performed regularly.
- Although METFORMIN PHARMC alone never causes hypoglycaemia, caution is advised when it is used in combination with insulin or sulphonylureas.

Other medicines and METFORMIN PHARMC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 METFORMIN PHARMC before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with METFORMIN PHARMC.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of METFORMIN PHARMC.

It is especially important to mention the following:

- 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),
- beta-2 agonists such as salbutamol or terbutaline (used to treat asthma),
- corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma),
- medicines that may change the amount of METFORMIN PHARMCin your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprime, vandetanib, isavuconazole, crizotinib, olaparib),
- other medicines used to treat diabetes.

METFORMIN PHARMC with alcohol

Avoid consumption of alcohol or alcohol containing medicine while taking METFORMIN PHARMC since this may increase the risk of lactic acidosis (see section ‘Warnings and precautions’).

METFORMIN PHARMC with food and drink

METFORMIN PHARMC can be taken with or after food.

Pregnancy, breastfeeding and fertility

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

METFORMIN PHARMC is not recommended if you are pregnant or breastfeeding or if you are planning to breastfeed your baby.

Driving and using machines

METFORMIN PHARMC on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines. However, take special care if you take METFORMIN PHARMC together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides). Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in

concentration. Do not drive or use machines if you start to feel these symptoms.

3. How to take METFORMIN PHARMC

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

Always take this medicine as the doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults: The usual starting dose is one 500 mg tablet three times a day, or one 850 mg or 1000 mg tablet twice a day, with or after food. Your doctor may adjust your dose after 10 to 15 days.

Children and adolescents: METFORMIN PHARMC can be used in children from 12 years of age and adolescents. The usual starting dose is 500 mg or 850 mg once daily, given during meals or after meals. Your doctor may adjust your dose after 10 to 15 days.

Elderly: METFORMIN PHARMC dose in the elderly should be adjusted based on renal function.

If you take more METFORMIN PHARMC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you have taken more METFORMIN PHARMC than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are non-specific such as vomiting, bellyache

(abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat. If you experience some of these symptoms, you should seek immediate~~ly~~ medical attention, as lactic acidosis may lead to coma. Stop taking METFORMIN PHARMC immediately and contact a doctor or the nearest hospital straight away

If you forget to take METFORMIN PHARMC

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

4. Possible side effects

METFORMIN PHARMCcan have side effects.

Not all side effects reported for METFORMIN PHARMC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking METFORMIN PHARMC, please consult your health care provider for advice.

If any of the following happens, stop giving METFORMIN PHARMC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to METFORMIN PHARMC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequently

METFORMIN PHARMC 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 METFORMIN PHARMC and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

• Digestive problems, such as feeling sick (nausea), being sick (vomiting), diarrhoea, bellyache (abdominal pain) and loss of appetite. These side effects most often happen at the beginning of the treatment with METFORMIN PHARMC. It helps if you spread the doses over the day and if you take METFORMIN PHARMC with or straight after a meal.

If symptoms continue, stop taking METFORMIN PHARMC and talk to your doctor.

- Changes in taste.

Less frequent

- Abnormalities in liver function tests or hepatitis (inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes). If this happens to you, stop taking METFORMIN PHARMC and talk to your doctor.
- Skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).
- Low vitamin B12 levels in the blood.

Children and adolescents

Limited data in children and adolescents showed that adverse events were similar in nature and severity to those reported in adults.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of METFORMIN PHARMC.

5. How to store METFORMIN PHARMC

Store all medicines out of reach of children.

- Store in cool and dry place at or below 25 ºC.
- *Blisters:* Do not remove the blisters from the outer carton until required for use.
- *HDPE bottles:* Store in the original container.
- Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What METFORMIN PHARMCcontains

- The active substance is metformin hydrochloride.

  Each Metformin 500 mg PharmC tablet contains 500 mg metformin hydrochloride.

  Each Metformin 850 mg PharmC tablet contains 850 mg metformin hydrochloride.

  Each Metformin 1000 mg PharmC tablet contains 1000 mg metformin hydrochloride.

  Sugar free.
- The other ingredients:

Tablet core: magnesium stearate, povidone K 30, povidone K 90, pregelatinised starch.

Film-coating: HPMC 2910/Hypromellose, macrogol/PEG, titanium dioxide.

What METFORMIN PHARMC looks like and contents of the pack

METFORMIN 500 mg PHARMC: White to off white, round biconvex film-coated tablets having “G” debossing on one side and plain on other side.

METFORMIN 850 mg PHARMC: White to off white, round biconvex film-coated tablets having “G” and “11” debossing on one side and plain on other side.

METFORMIN 1000 mg PHARMC: White to off white, oval biconvex scored film-coated tablets debossed with "G" and "12" on either side of score line on one side and plain on other side.

METFORMIN PHARMC is packed in:

500 mg & 850 mg:

Blister Pack

- 10 tablets in blister pack (PVC-aluminum) packed in an outer carton as 60, 90,120 tablets or

HDPE bottles

- 60 tablets in HDPE bottles (high-density polyethylene) with child resistant caps (polypropylene) and desiccant sachet activated carbon 1g, or
- 1000 tablets in HDPE bottles (high-density polyethylene) with continues thread caps (polypropylene) and desiccant sachet activated carbon 2 g

1000 mg:

Blister Pack

- 15 tablets in blister pack (PVC-aluminum) packed in an outer carton as 30, 60, 90,120 tablets or

HDPE bottles

- 60 tablets in HDPE bottles (high-density polyethylene) with child resistant caps (polypropylene) and desiccant sachet activated carbon 1g, or
- 1000 tablets in HDPE bottles (high-density polyethylene) with continues thread caps (polypropylene) and desiccant sachet activated carbon 2 g

Not all packs and pack sizes are marketed.

Holder of Certificate of Registration

29 Victoria Link

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Irene, 0178

RSA

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Registration numbers

METFORMIN 500 mg PHARMC: 56/21.2/0102

METFORMIN 850 mg PHARMC: 56/21.2/0103

METFORMIN 1000 mg PHARMC: 56/21.2/0104

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website