SCHEDULING STATUS: S3

MYLAN METFORMIN 500 Film-coated tablets

MYLAN METFORMIN 850 Film-coated tablets

MYLAN METFORMIN 1000 Film-coated tablets

Metformin hydrochloride

Sugar free

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MYLAN METFORMIN 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 MYLAN METFORMIN is and what it is used for
2. What you need to know before you take MYLAN METFORMIN
3. How to take MYLAN METFORMIN
4. Possible side effects
5. How to store MYLAN METFORMIN
6. Contents of the pack and other information

1. What MYLAN METFORMIN is and what it is used for

What MYLAN METFORMIN is

MYLAN METFORMIN is an oral hypoglycaemic medicine and helps to control the level of sugar in the blood.

What it is used for

- MYLAN METFORMIN is indicated for treatment of type II diabetes mellitus in adults, particularly in

overweight patients, when dietary management and exercise does not result in acceptable glycaemic control (control of levels of blood sugar).

- MYLAN METFORMIN can be given alone as basic therapy, or can be administered in combination with other oral antidiabetic medicines or with insulin.
- MYLAN METFORMIN can be given alone or in combination with insulin in children over 12 years of age and adolescents with type II diabetes.

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

Do not take MYLAN METFORMIN

- If you are hypersensitive (allergic) to metformin hydrochloride or any of the other ingredients of MYLAN METFORMIN (listed in section 6).
- You are pregnant or plan to become pregnant.
- You are breastfeeding.
- You have kidney problems e.g. severely reduced kidney function.
- You have pancreas problems.
- If you suffer from any type of metabolic acidosis (too much acid is in your body) such as lactic acidosis (see Warnings and Precautions) or diabetic ketoacidosis (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.
- If you suffer from diabetic pre-coma (dangerously high blood sugar or dangerously low blood sugar).
- If you suffer from sudden onset conditions that can cause kidney problems. Conditions such as:
  - Dehydration: if you lost too much water from your body, due to long-lasting or severe diarrhoea, or if you have vomited several times in a row.
  - Severe infection
  - Have severe problems with your blood circulation (such as shock).
  - If you need to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your bloodstream.
- If you suffer from sudden onset or long-lasting conditions which may cause low blood oxygen (hypoxia).

- Conditions such as:
  - Heart failure or if you recently had a heart attack.
  - Difficulty in breathing – if your lungs cannot supply enough oxygen to your organs.
  - Shock – severe problems with your blood circulation that causes reduced oxygen delivery or increased oxygen consumption.
- If you drink a lot of alcohol or if you your liver is not functioning optimal.

Warnings and precautions

Take special care with MYLAN METFORMIN

- ***Risk of lactic acidosis***

MYLAN METFORMIN may cause a very rare, but very serious side effect called lactic acidosis, that most often occurs if your kidneys or blood circulation system are not working properly.

The risk of developing lactic acidosis is also increased with:

- Uncontrolled diabetes.
- Ketosis (a metabolic state that occurs when your body burns fat for energy instead of glucose).
- Extended fasting.
- Excessive alcohol intake.
- Liver problems.
- Any medical conditions in which a part of the body has a reduced supply of oxygen (such as a sudden onset severe heart disease) as well as certain medicines (see Other medicines and MYLAN METFORMIN).

In case of dehydration (if you lost too much water from your body, due to long-lasting or severe diarrhoea, or if you have vomited several times in a row or have insufficient fluid intake) MYLAN METFORMIN should be briefly stopped, and you should contact your health care professional.

Medicines such as certain blood pressure medicine, medicine that increases urine output (diuretics), and anti-inflammatory medicine can cause sudden kidney problems and should be used with caution. Inform your health care provider if you are taking any such medicine.

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

Symptoms of lactic acidosis include:

- Stomach-ache.
- Difficulty in breathing.

- A significant and potentially dangerous drop in body temperature followed by coma.

- During treatment with MYLAN METFORMIN, 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.
- Do not use MYLAN METFORMIN if you suffer from acute or unstable heart failure (occurs when the heart muscle does not pump blood as well as it should) (see Do not take MYLAN METFORMIN).
- ***Taking medicine than contains iodine***

  Stop taking MYLAN METFORMIN for a short period if you are going to receive medicine containing iodine used for x-ray-based imaging. Your doctor will decide when you must stop and when to restart your treatment with MYLAN METFORMIN.
- ***Surgery***

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

Other precautions

- You should continue with a balanced diet, which consists of regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.
- The usual tests for diabetes monitoring should be performed regularly.
- MYLAN METFORMIN on its own does not cause hypoglycaemia (a blood glucose level that is too low). However, if you take MYLAN METFORMIN together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia.
- Do not take MYLAN METFORMIN if you are suffering from conditions, which may cause dehydration, serious infections, trauma or on low calorie intake (see Do not take MYLAN METFORMIN).
- If you are on long-term MYLAN METFORMIN treatment, your Vitamin B12 levels should be checked at least once a year since MYLAN METFORMIN may cause malabsorption of Vitamin B12, which may result in a disease called megaloblastic anaemia (lack of enough red blood cells to carry adequate oxygen to your body’s tissue which can make you feel weak and tired) (see Possible side effects).

Children and adolescents

MYLAN METFORMIN can be used in children from 12 years of age and adolescents. The diagnosis of type 2 diabetes mellitus must be confirmed before treatment with MYLAN METFORMIN is initiated.

Other medicines and MYLAN METFORMIN

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

Tell your doctor if you are taking any of the following medicines:

- *Alcohol:* Avoid consumption of alcohol and alcohol-containing medicines.
- *Iodinated contrast agents:* The use of contrast medicine that contains iodine given to you if you are going for an X-rays may lead to renal failure and lactic acidosis.
- *Glucocorticoids:*
  - These medicines have intrinsic hyperglycaemic activity. More frequent blood glucose monitoring should be performed, especially at the beginning of treatment.
  - Used to treat a variety of conditions, such as severe inflammation of the skin or in asthma.
- ACE-inhibitors:
  - Certain medicines for the treatment of high blood pressure.
  - These medicines may decrease the blood glucose levels.
- *Anticoagulants:* Dose adjustments should be considered as it has been reported to ~~diminish~~ weaken the activity of warfarin.
- *Sulphonylurea:*
  - Medicines that control blood sugar levels in patients with type 2 diabetes.
  - Concomitant treatment with sulphonylurea may cause hypoglycaemia.
- *Vitamins:* Long-term treatment with MYLAN METFORMIN may cause vitamin B12 malabsorption in the gastrointestinal tract, thus a dose reduction of MYLAN METFORMIN should be considered.
- Medicines which increase urine production (diuretics).
- Medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- Medicines that may change the amount of MYLAN METFORMIN in your blood, especially if you have reduced kidney function such as:
  - Verapamil (a medicine use to treat high blood pressure).

- Rifampicin (an antibiotic used to treat bacterial infections, including tuberculosis).
- Cimetidine (a medicine used to treat sores in your stomach and heartburn).
- Dolutegravir (a medicine used to treat HIV/AIDS).
- Ranolazine (a medicine used to treat ongoing chest pain – angina)
- Trimethoprim (an antibiotic used to treat bladder infections).
- Vandetanib, crizotinib, olaparib (anti-cancer medicines).
- Isavuconazole (a medicine used to treat fungal infections).

MYLAN METFORMIN with food, drink and alcohol

Avoid consumption of alcohol and alcohol-containing medicine since this may increase the risk of lactic acidosis (see Warnings and precautions).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, 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 MYLAN METFORMIN.

You should not take MYLAN METFORMIN if you are pregnant or breastfeeding your baby.

Driving and using machines

MYLAN METFORMIN on its own does not cause hypoglycaemia (a blood glucose level which is too low). It is not always possible to predict to what extent MYLAN METFORMIN 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 MYLAN METFORMIN affects them.

MYLAN METFORMIN is sugar free.

3. How to take MYLAN METFORMIN

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

Always take MYLAN METFORMIN exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose is:

It is important that MYLAN METFORMIN tablets be taken in divided doses with meals.

Adults

- Initially one 500 mg tablet two to three times a day, or one 850 mg or 1000 mg tablet twice a day,

with or after food.

- After 10 to 15 days the dose should be adjusted according to blood glucose measurements. A slow increase in dose may improve gastrointestinal tolerability.
- Good diabetic control may be achieved within a few days, but it is not unusual for the full effect to be delayed for up to two weeks.
- If control is incomplete, a cautious increase in dosage to a maximum of 2 550 mg daily is justified. Once control has been obtained, it may be possible to reduce the dosage of MYLAN METFORMIN.

Children and adolescents

- MYLAN METFORMIN 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. After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements.
- A slow increase of dose may improve gastrointestinal tolerability.
- The maximum recommended dose of metformin is 2 000 mg daily, taken as 2 or 3 divided doses.

Elderly

MYLAN METFORMIN dose in the elderly should be adjusted based on renal function.

Combination therapy

- See Other medicines and MYLAN METFORMIN and Warnings and precautions.
- Your doctor will tell you how long your treatment with MYLAN METFORMIN will last.
- If you have the impression that the effect of MYLAN METFORMIN is too strong or too weak, tell your doctor or pharmacist.

If you take more MYLAN METFORMIN than you should

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

If you forget to take MYLAN METFORMIN

If you forget to take a dose take it as soon as you remember. If it is almost time for your next dose though, do not double the dose but rather carry on as before.

If you stop taking MYLAN METFORMIN

Do not stop treatment early because you feel better.

4. Possible side effects

MYLAN METFORMIN can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth 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 allergic reaction to MYLAN METFORMIN. 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:

- Lactic acidosis may occur particularly if your kidneys are not working properly and is a medical emergency which must be treated in hospital. Symptoms of lactic acidosis are non-specific (see Warning and precautions).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Nausea.
- Vomiting.
- Constipation.
- Diarrhoea.
- Anorexia.
- Metallic taste.
- Low Vitamin B12 levels and folic acid in the blood.

The following side effects have been reported less frequently:

- Skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).
- Lack of enough red blood cells to carry adequate oxygen to your body’s tissue which can make you

feel weak and tired (megaloblastic anaemia).

- Low blood sugar (hypoglycaemia).

The following side effects have been reported but the frequency is unknown:

- 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).
- Body produces high levels of blood acids called ketone (ketoacidosis).
- High levels of ketones (which occur when cells are broken down for energy) are present in the urine (ketonuria).

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 on the SAHPRA website at: https://medsafety.sahpra.org.za/#download, via email at: adr@sahpra.org.za or via telephone at: 0125010311. By reporting side effects, you can help provide more information on the safety of MYLAN METFORMIN.

5. How to store MYLAN METFORMIN

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in a cool, dry place.
- Store in the original package/ container.
- Protect from light.
- Do not store in a bathroom.
- 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 MYLAN METFORMIN contains

The active substance is metformin.

The other ingredients are*:*

1.3.2 Patient Information Leaflet

MYLAN METFORMIN 500 and MYLAN METFORMIN 850:

Povidone K-30, magnesium stearate.

Film-coating: Hydroxypropyl methyl cellulose

OR

Opadry clear 20C59060 (composition: hypromellose 6 cP, hydroxypropyl cellulose, hypromellose 15 cP, macrogol 400, macrogol 8000).

MYLAN METFORMIN 1000:

Povidone K-30, magnesium stearate.

Film-coating: Opadry clear 20C59060 (composition: hypromellose 6 cP, hydroxypropyl cellulose, hypromellose 15 cP, macrogol 400, macrogol 8000).

What MYLAN METFORMIN looks like and contents of the pack

What MYLAN METFORMIN looks like:

MYLAN METFORMIN 500: White, round, biconvex, film-coated tablets.

MYLAN METFORMIN 850: White, round, biconvex, film-coated tablets.

MYLAN METFORMIN 1000: White, oval, film-coated tablet debossed “MF” and “3” on either side of the break line on one side and “G” on the other side.

Contents of the pack:

MYLAN METFORMIN 500:

White opaque high-density polyethylene (HDPE) bottle with white opaque polypropylene (PP) cap in pack sizes of 56, 84, 90, 100 or 500 tablets.

Blister pack comprising of clear transparent PVC film with backing of aluminium foil coated with heat seal lacquer. Blister strips of 14 tablets packed into unit cartons of 56 or 84 tablets. Blister strips of 15 tablets packed into unit cartons of 90 tablets.

MYLAN METFORMIN 850:

White opaque high-density polyethylene (HDPE) bottle with white opaque polypropylene (PP) cap in pack sizes of 60, 84 or 300 tablets.

Blister pack comprising of clear transparent PVC film with backing of aluminium foil coated with heat seal lacquer. Blisters strips of 14 tablets are packed into unit cartons of 28, 56 or 84 tablets. Blister strips of 15 tablets packed into unit cartons of 60 tablets.

MYLAN METFORMIN 1000:

White opaque high-density polyethylene (HDPE) bottle with white opaque polypropylene (PP) cap in pack sizes of 30, 100 and 1 000 tablets.

Blister pack comprising of clear transparent PVC film with backing of aluminium foil coated with heat seal lacquer. Blisters are packed in an outer carton in pack sizes of 56, 60, 100 or 300 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

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MYLAN METFORMIN 500: 33/21.2/0204

MYLAN METFORMIN 850: 33/21.2/0205

MYLAN METFORMIN 1000: 45/21.2/0669

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.