

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

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METFORMIN 500 mg XR UNIMED (tablet)

METFORMIN 750 mg XR UNIMED (tablet)

METFORMIN 1000 mg XR UNIMED (tablet)

Metformin hydrochloride. Sugar free.

Read all of this leaflet carefully before you start taking **METFORMIN XR UNIMED**

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

1. What METFORMIN XR UNIMED is and what it is used for

METFORMIN XR UNIMED contains the active ingredient metformin, and belong to a group of medicines called biguanides, which is used for the treatment of Type 2 (noninsulin dependent) diabetes mellitus when diet and exercise changes alone have not been enough to control blood glucose (sugar).

Insulin is a hormone that enables body tissues to take glucose from the blood and to use it for energy or for storage for future use. People with Type 2 diabetes do not make enough insulin in their pancreas or their body does not respond properly to the insulin it does make. This causes a build-up of glucose in the blood which can cause a number of serious long-term problems so it is important that you continue to take your medicine, even though you may not have any obvious symptoms. METFORMIN XR UNIMED makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

METFORMIN XR UNIMED tablets are specially made to release the medicine slowly in your body. METFORMIN XR UNIMED can be given alone as initial therapy or can be administered in combination with other oral antidiabetic medicines or with insulin.

2. What you need to know before you take METFORMIN XR UNIMED

Do not take METFORMIN XR UNIMED:

- If you are hypersensitive to metformin hydrochloride or any of the ingredients of METFORMIN XR UNIMED.
 - You have severe complications of your diabetes such as diabetic ketoacidosis, a metabolic state resulting from a profound lack of insulin.
 - Your kidneys do not work properly or do not work at all.
 - You suffer from short term conditions that may affect your kidney function e.g.
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dehydration, severe infection, shock, administration of iodinated contrast media

through the veins.

- You suffer from 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 have liver problems, suffer from acute alcohol intoxication, alcoholism (acute or chronic)
- If you are pregnant.

Take special care with METFORMIN XR UNIMED:

- 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.
- Lactic acidosis is a rare, but serious and life-threatening complication that can occur when lactic acid builds up in the blood stream faster than it can be removed. Symptoms include nausea, vomiting, abdominal pain and low body temperature. This complication could happen when METFORMIN XR UNIMED accumulates in your blood, especially if you have serious kidney dysfunction. METFORMIN XR UNIMED treatment should be stopped and you should be hospitalised.
- Since METFORMIN XR UNIMED is excreted by kidney, tests to determine if the kidneys are working should be conducted:
 - annually in patients with normal renal function,
 - At least two to four times a year if you suffer from high serum creatinine levels and if you are older than 65 years old.
- Other precautions:
 - If you are taking vitamin B12, METFORMIN XR UNIMED may cause malabsorption of

vitamin B12. You should check your vitamin B12 levels annually.

- METFORMIN XR UNIMED should be discontinued 48 hours before surgery with general anaesthesia and should not be usually resumed earlier than 48 hours afterwards.
- If you are administered an iodinated contrast agent (which can cause renal failure), METFORMIN XR UNIMED should be stopped prior and you should only start taking METFORMIN XR UNIMED again once it has been established that your kidneys are working normally.
- Although METFORMIN XR UNIMED alone never causes hypoglycaemia, caution is advised when it is used in combination with insulin or sulphonylureas.

Taking other medicines with METFORMIN XR UNIMED:

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

This is because the active agent in METFORMIN XR UNIMED can affect the way some medicines work. Also, some medicines can affect the way METFORMIN XR UNIMED works.

Other medicines and METFORMIN XR UNIMED:

Combinations that should be avoided when taking METFORMIN XR UNIMED:

- Drinking alcohol and alcohol-containing medications.
 - Administration of iodinated contrast medicines in your veins as this may lead to kidney failure, resulting in METFORMIN XR UNIMED accumulation and a risk of lactic acidosis, where lactic acid builds up in the bloodstream faster than it can be removed causing nausea and vomiting. METFORMIN XR UNIMED should be discontinued prior to, or at the time of the test and not reinstituted until 48 hours afterwards, and only after renal function
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has been re-evaluated and found to be normal.

Take special care when using any of the following medications together with

METFORMIN XR UNIMED

- Glucocorticoids (systemic and local routes) that are used to treat conditions that involve inflammation, beta-2-agonist medicines that opens the airways especially in patients with asthma, and diuretics (medication that helps your body get rid of extra fluid)
- ACE-inhibitors (medicines used to treat high blood pressure)
- Cimetidine (medicines used to treat stomach ulcers)
- Anticoagulants (medicines used to thin the blood)
- Sulphonylurea (medicines that control your blood glucose levels)
- Vitamins (Long term use of METFORMIN XR UNIMED may cause malabsorption of Vitamin B12 in the gut)
- Carbonic anhydrase inhibitors such as topiramate, zonisamide, acetazolamide, dichlorophenamide (medicines used to treat glaucoma or seizure disorders)
- Medicines that slow down the elimination of METFORMIN XR UNIMED from the body such as ranolazine, vandetanib, dolutegravir

METFORMIN XR UNIMED with food and drink

METFORMIN XR UNIMED should be taken with food.

Pregnancy, breastfeeding and fertility

METFORMIN XR UNIMED must not be taken during pregnancy.

METFORMIN XR UNIMED passes into breastmilk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking METFORMIN XR UNIMED.

Driving and using machines

METFORMIN XR UNIMED on its own has no effect on the ability to drive or to use machines. Care should however be taken when the METFORMIN XR UNIMED range is combined with other anti-diabetic medicines such as sulphonylureas or insulin, as this may cause low blood glucose levels and might interfere with your driving ability.

3. How to take METFORMIN XR UNIMED

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

Always take METFORMIN XR UNIMED exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with METFORMIN XR UNIMED will last. If you have the impression that the effect of METFORMIN XR UNIMED is too strong or too weak, talk to your doctor or pharmacist.

Your individual dose will be decided by your doctor after laboratory tests and examinations.

Always take this medicine as the doctor has instructed you.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- You must take the tablets during or immediately after meals.

METFORMIN 500 mg XR UNIMED:

The usual starting dose is one tablet daily taken with the evening meal. Your doctor may adjust

your dose after 10 to 15 days.

The maximum recommended dosage is usually not more than 4 tablets daily.

METFORMIN 750 mg XR UNIMED:

The usual starting dose is one tablet daily taken with the evening meal. Your doctor may adjust your dose after 10 to 15 days.

The maximum recommended dosage is 3 tablets daily.

METFORMIN 1000 mg XR UNIMED:

The usual starting dose is one tablet daily taken with the evening meal at a maximum recommended dose of 2 tablets per day.

METFORMIN XR UNIMED is intended as maintenance therapy for patients currently treated with either

1 000 mg or 2 000 mg metformin hydrochloride.

Your doctor will tell you how long your treatment with METFORMIN XR UNIMED will last. If you have the impression that the effect of METFORMIN XR UNIMED is too strong or too weak, tell your doctor or pharmacist.

If you take more METFORMIN XR UNIMED than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Take the medicine pack with you. This is so the doctor knows what you have taken.

Hypoglycaemia can occur when METFORMIN XR UNIMED range is given concomitantly with a sulphonylurea, insulin or alcohol. Lactic acidosis may develop. Treatment is supportive and symptomatic.

If you forget to take METFORMIN XR UNIMED

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking METFORMIN XR UNIMED

Do not stop taking this medicine without talking to your doctor first.

4. Possible side effects

METFORMIN XR UNIMED can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- If your body breaks out in a severe rash characterised by blisters or you experience severe itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to METFORMIN XR UNIMED. 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:

- Nausea, vomiting, diarrhoea or abdominal pain- this could be a sign of lactic acidosis (see 'Take special care with METFORMIN XR UNIMED above')

Tell your doctor if you notice any of the following:

The following side effects occur frequently:

- Taste disturbances
- Nausea, vomiting, diarrhoea, abdominal pain
- Loss of appetite
- Decrease in vitamin B12 absorption.

The following side effects occur less frequently:

- Abnormalities in liver function tests
- Hepatitis (inflamed liver) resolving on METFORMIN XR UNIMED range discontinuation

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. 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 METFORMIN XR UNIMED.

5. How to store METFORMIN XR UNIMED

Store all medicines out of reach of children.

Store at or below 25 °C

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the carton. 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 XR UNIMED contains

The active substance in each METFORMIN 500 mg XR UNIMED tablet is: 500 mg metformin hydrochloride.

The active substance in each METFORMIN 750 mg XR UNIMED tablet is: 750 mg metformin hydrochloride.

The active substance in each METFORMIN 1000 mg XR UNIMED tablet is: 1000 mg metformin hydrochloride.

The other ingredients of METFORMIN XR UNIMED are:

hypromellose K-100 M, povidone K-30, purified water, colloidal anhydrous silica, hypromellose K-15 M, magnesium stearate, opadry OY-7300.

What METFORMIN XR UNIMED looks like and contents of the pack

METFORMIN 500 mg XR UNIMED:

White, Oval shaped, film coated tablets, debossed "MT" on one side and "500" on other side.

METFORMIN 750 mg XR UNIMED:

White, Oval shaped, film coated tablets, debossed "MT" on one side and "750" on other side.

METFORMIN 1000 mg XR UNIMED:

White, Oval shaped, film coated tablets, debossed "MT" on one side and "1000" on other side.

METFORMIN 500 mg XR UNIMED, 750 mg and 1000 mg Blister

Pack:

Multiple blisters may be packed in a varnished, printed cardboard carton. **METFORMIN XR UNIMED** (all strengths) are presented in clear, transparent PVC/PVDC and Aluminium foil blister packs.

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

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METFORMIN 750 mg XR UNIMED: 58/21.2/0191

METFORMIN 1000 mg XR UNIMED: 58/21.2/0192

Access to the corresponding Professional Information

The Professional Information is contained in the packaging of METFORMIN 500 mg / 750 mg /
1 000 mg XR UNIMED