

Metformin Hydrochloride Tablets 500mg (Metformin Hydrochloride)

Please read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious or you notice any not listed in this leaflet, please tell your doctor or pharmacist.

The name of this medicine is Metformin Hydrochloride Tablets 500mg (also referred to as Metformin Hydrochloride throughout this leaflet).

In this leaflet:

- 1** What this medicine is and what it is used for
- 2** Before you take
- 3** How to take
- 4** Possible side effects
- 5** How to store
- 6** Further information

1 What this medicine is and what it is used for

Metformin Hydrochloride Tablets 500mg belong to a group of medicines called biguanide oral anti-hyperglycaemic agents. It works by lowering your blood-sugar level.

Metformin Hydrochloride is used to treat non-insulin dependent diabetes when a change of diet has failed to reduce blood sugar levels, particularly if overweight.

It may be used alone as initial therapy or along with another group of medicines called sulphonylureas, which stimulate the pancreas to produce more insulin.

Sometimes Metformin Hydrochloride is also used to treat patients suffering from insulin dependent diabetes, who are over weight (obese) and whose symptoms are poorly controlled.

If your blood sugar levels are not controlled, it can lead to serious problems such as kidney damage, amputations and blindness. Metformin Hydrochloride is thought to work by decreasing the amount of sugar absorbed from food through the stomach, by helping the body respond better to the insulin it makes naturally and by decreasing the amount of sugar produced by the liver and kidneys.

2 Before you take

Do not take Metformin Hydrochloride Tablets 500mg if:

- you are allergic to Metformin Hydrochloride or any of the other ingredients.
- you have any kind of kidney or liver disease.
- you have serious diabetic complications such as loss of consciousness caused by either very high or very low blood sugar levels (diabetic coma) and a lack of insulin which leads to high blood sugar levels, ketones in the urine and certain acids in the blood (ketoacidosis).
- you have heart complications such as heart failure (even if the condition is under control) or recently had a heart attack.
- you have a history of a build up of lactic acid in the blood (lactic acidosis), which may be associated with shock and breathing difficulties.
- you regularly consume excess alcohol.
- you have a severe infection or injury.
- you suffer from a loss or lack of water in the body (dehydration).
- you have a severe disease of the blood vessels.

If any of the above apply to you, please consult your doctor or pharmacist.

Take special care with Metformin Hydrochloride:

- If you are to undergo diagnostic tests (using iodinated contrast media) – you should tell your doctor as you may need to stop your medication.
- if you continuously use Metformin Hydrochloride. It may reduce your vitamin B12 level and should be annually monitored by your doctor.
- if you suffer from kidney problems, particularly if elderly.

If any of the above apply to you, please consult your doctor or pharmacist.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Other medicines may interfere with the actions of Metformin Hydrochloride. You should tell your doctor if you are taking any of the following:

- cimetidine, for stomach ulcers and indigestion.
- medicines to prevent clotting of the blood, such as warfarin (anticoagulants).
- medicines for high blood pressure, such as captopril (ACE inhibitors).
- medicines for depression, such as moclobemide (MAO inhibitors).
- diazoxide, for high blood pressure.
- medicines for lowering high blood pressure, such as propranolol (beta-blockers).
- medicines for inflammatory and allergic conditions, such as beclometasone (corticosteroids).
- oral contraceptives.
- medicines for fluid retention, such as bumetanide (diuretics).
- medicines for high cholesterol, such as ezetimibe (clofibrates).
- medicines for diabetes such as glibenclamide (sulphonylureas) or insulin.

Taking with alcohol

If you drink alcohol whilst taking Metformin Hydrochloride it may interfere with the actions of the medicine.

Pregnancy and breast-feeding

If you are pregnant, thinking of becoming pregnant or breast-feeding, Metformin Hydrochloride should not be taken unless told to do so by your doctor.

Driving or using machinery

Metformin Hydrochloride should not affect your ability to drive or operate machinery.

Important information about some of the ingredients

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this product.

continued...

3 How to take

You should always take this medicine as prescribed by your doctor. Do not take more than the doctor has told you to. Read and follow the instructions on the pharmacist's label. If you are not sure about anything, please ask your doctor or pharmacist.

- These tablets are for oral administration.
- Metformin Hydrochloride Tablets 500mg should be taken with or after food.

The doses stated below are guidelines only. You should always take this medicine as prescribed by your doctor.

Adults

The usual dose is one 500mg tablet three times a day. This medicine may take a few days to 2 weeks to control your condition. Your doctor may increase the dosage to a maximum of 3000mg per day until your condition is under control.

Elderly

Your doctor will monitor your condition if you have kidney problems.

Children

Metformin Hydrochloride Tablets 500mg are **not** recommended for children.

If you forget to take Metformin Hydrochloride

Take as soon as you remember. Do not take a double dose to make up for the forgotten individual dose.

If you have taken more Metformin Hydrochloride than you should

Contact your doctor immediately or go to the nearest accident and emergency department. Remember to take this leaflet or any remaining tablets with you.

4 Possible side effects

Metformin Hydrochloride is usually well tolerated. However, like most medicines it can cause unwanted side effects in some patients.

Serious side effect:

There are only a few reported cases but some people have developed a condition known as lactic acidosis whilst taking Metformin Hydrochloride.

Lactic acidosis is caused by a build up of lactic acid in the blood (produced when glucose is turned into energy without oxygen).

Possible symptoms of lactic acidosis:

- unexplained weight loss
- feeling sick (nausea)
- being sick (vomiting)
- general feeling of being unwell
- pain in the belly region
- increased breathing rate

If you have or think you may have lactic acidosis, you should go to the hospital immediately as it is a medical emergency.

Side effects (usually short-term)

- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- weight loss

These side effects may be avoided by taking your medicine with or after food.

If you have any of these side effects important to continue taking your medicine as they normally disappear after a short time.

Other side effect

- decreased vitamin B12 absorption

If any of these side effects get serious or you notice any not listed, please tell your doctor or pharmacist.

5 How to store

Keep out of the reach and sight of children.

Store in the original package.

Do not take after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of that month.

If your doctor tells you to stop taking your medicine, you should return any remaining tablets to the pharmacist, unless your doctor tells you to keep them.

6 Further information

What Metformin Hydrochloride Tablets 500mg contain:

- **The active ingredient is:** Metformin Hydrochloride 500mg.
- **Other ingredients are:** microcrystalline cellulose, sodium starch glycolate, povidone k-28, colloidal anhydrous silica and magnesium stearate.
- **Film coating is:** opadry white OY-L-28900 consisting of lactose monohydrate, hypromellose, titanium dioxide (E171) and macrogol 4000.
- **This medicine contains lactose** (see important information about some of the ingredients at the end of section 2)

What Metformin Hydrochloride Tablets 500mg look like and the contents of the pack:

Metformin Hydrochloride Tablets 500mg are white, oblong, film-coated tablets with a score notch on one side and marked M500 on the other.

They are available in packs of 28, 30, 56, 84 and 120 tablets. Not all pack sizes may be marketed

REMEMBER

This medicine is only for YOU. Do not offer it to anybody else. It may harm them even if their symptoms seem to be the same as yours.

This information applies only to Metformin Hydrochloride Tablets 500mg.

Marketing Authorisation Holder and Manufacturer:

Tillomed Laboratories Ltd
3 Howard Road.
Eaton Socon, St Neots
Cambridgeshire,
PE19 8ET
United Kingdom.

Product Licence Number:

Metformin Hydrochloride Tablets 500mg:
PL 11311/0466

Date of revision: October 2009



Hard to Read? Phone 0800 970 6115 for help