

Package leaflet: Information for the user

**Metformin hydrochloride
500 mg, 750 mg, 1000 mg
Prolonged-release Tablets**

metformin hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The full name of this medicine is Metformin hydrochloride 500, 750, 1000 mg Prolonged-release Tablets but within the leaflet it will be referred to as Metformin hydrochloride Tablets.

What is in this leaflet

1. What Metformin hydrochloride Tablets is and what it is used for
2. What you need to know before you take Metformin hydrochloride Tablets
3. How to take Metformin hydrochloride Tablets
4. Possible side effects
5. How to store Metformin hydrochloride Tablets
6. Contents of the pack and other information

1. What Metformin hydrochloride Tablets is and what it is used for

Metformin hydrochloride Tablets contains the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of diabetes.

Metformin hydrochloride Tablets is used for the treatment of Type 2 (also known as non-insulin dependent) diabetes mellitus in adults 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 hydrochloride makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Metformin hydrochloride Tablets is associated with either a stable body weight or modest weight loss.

Metformin hydrochloride Tablets is specially made to release the drug slowly in your body and therefore are different to many other types of tablet containing metformin.

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

2. What you need to know before you take Metformin hydrochloride Tablets Do not take Metformin hydrochloride Tablets:

- If you are **allergic** to metformin or to any of the other ingredients of this medicine (listed in section 6).
 - If you have long-term **liver** problems.
 - If you have severely reduced kidney function.
 - If you have uncontrolled diabetes, with, for example, severe hyperglycaemia (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.
 - If you have lost too much water from your body (dehydration) such as due to long lasting or severe diarrhoea or if you have vomited several times in a row. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see "Warnings and precautions").
 - If you have a **severe infection** such as lung or kidney infection. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis. (see "Warnings and precautions")
 - If you have been treated for **heart problems** or have recently had a **heart attack** or have severe circulatory problems or breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see "Warnings and precautions")
 - If you are a **heavy drinker of alcohol**.
 - If you are younger than 18 years of age.
- If any of the above applies to you, talk to your doctor, before you start taking this medicine.

- Make sure you ask your doctor for advice, if:
- you need to have an examination such as X-ray or other imaging examination involving the injection of contrast medicines that contain iodine into your bloodstream (see "Other medicines and Metformin hydrochloride Tablets below).
 - you need to have major surgery.

You must stop taking Metformin hydrochloride Tablets for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Warnings and precautions

Talk to your doctor before taking Metformin hydrochloride Tablets

After you have started taking your medicine:

If you have diabetes you should have your blood or urine tested for sugar regularly. During treatment with Metformin hydrochloride Tablets 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.

Risk of lactic acidosis

Metformin hydrochloride Tablets 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 hydrochloride Tablets 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 Metformin hydrochloride Tablets 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 hydrochloride Tablets during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Metformin hydrochloride Tablets.

Metformin hydrochloride Tablets on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin hydrochloride Tablets 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.

You may see some remains of the tablets in your stools. Do not worry as this is normal for this type of tablet.

You should continue to follow any dietary advice that your doctor has given you and you should make sure that you eat carbohydrates regularly throughout the day.

Do not stop taking this medicine without speaking to your doctor

Children and adolescents

Children and adolescents should not use this medicine. It is not known if this medicine is safe and effective when used in children and adolescents under 18 years of age.

Other medicines and Metformin hydrochloride Tablets

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

Tell your doctor or pharmacist 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 hydrochloride Tablets. It is especially important to mention the following:

- medicines which increase urine production (diuretics water tablets)
- 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 such as prednisolone, mometasone, beclometasone (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma).
- other medicines used to treat diabetes.
- sympathomimetic medicines including epinephrine and dopamine used to treat

heart attacks and low blood pressure. Epinephrine is also included in some dental anaesthetics.

- medicines that may change the amount of metformin in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

Metformin hydrochloride Tablets with food, drink and alcohol

You should take Metformin hydrochloride Tablets with or immediately after food e.g. with your evening meal.

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, so that they may change your treatment. Do not take Metformin hydrochloride Tablets if you are pregnant.

It is recommended not to take this medicine if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines

Metformin hydrochloride Tablets taken on its own does not cause 'hypoglycaemia' (symptoms of low blood sugar, such as faintness, confusion and increased sweating) and therefore should not affect your ability to drive or use machinery.

You should be aware, however, that Metformin hydrochloride Tablets taken with other antidiabetic medicines can cause low blood sugar, so in this case you should take extra care when driving or operating machinery.

3. How to take Metformin hydrochloride Tablets

Your doctor may prescribe Metformin hydrochloride Tablets for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Metformin hydrochloride Tablets cannot replace the benefits of a healthy lifestyle. Continue to follow any advice about diet that your doctor has given you and get some regular exercise.

Dosage

Usually you will start treatment with 500 milligrams Metformin hydrochloride Tablets daily. After you have been taking Metformin hydrochloride Tablets for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams of Metformin hydrochloride Tablets. If you have reduced kidney function, your doctor may prescribe a lower dose

If you take insulin too, your doctor will tell you how to start Metformin hydrochloride Tablets

How to take the tablets

Normally, you should take the tablets once a day, with your evening meal.

In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tablets with food.

Swallow the tablets whole with a glass of water, do not chew, split or crush the tablets.

If, after some time, you think that the effect of Metformin hydrochloride Tablets is too strong or too weak, talk to your doctor or pharmacist.

Use in children and adolescents

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

Use in elderly

The dose will be determined after tests have been carried out on your kidney function.

If you take more Metformin hydrochloride Tablets than you should

If you take extra tablets by mistake you need not worry, but if you have unusual symptoms, contact your doctor. These symptoms may include weakness, confusion, fast breathing and new onset of nausea, vomiting or stomach pain. If the overdose is large, lactic acidosis is more likely and this is a medical emergency requiring treatment in hospital (see also under '4. Possible side effects').

If you forget to take Metformin hydrochloride Tablets

Take it as soon as you remember with some food. Do not take a double dose to make up for a forgotten dose.

If you stop taking Metformin hydrochloride Tablets

You should not stop taking this medicine without talking to your doctor first. If you stop taking Metformin hydrochloride Tablets, your blood sugar may rise again.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following side effects, stop taking Metformin hydrochloride Tablets and see your doctor immediately:

Very rare (may affect up to 1 in 10,000 people):

- Metformin hydrochloride Tablets 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 hydrochloride Tablets and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.
- Abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice. If you develop yellowing of the eyes and/or skin contact your doctor immediately.

Other possible side effects are listed by frequency as follows:

- Very common** (may affect more than 1 in 10 people):
 - Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. If you get these, do not stop taking the tablets as these symptoms will normally go away in about 2 weeks. It helps if you take tablets with or straight after a meal.

Common (may affect up to 1 in 10 people):

- Taste disturbance

Very rare (may affect up to 1 in 10,000 people):

- Decreased vitamin B₁₂ levels which may result in anaemia
- Skin rashes including redness, itching and hives.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metformin hydrochloride Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information What Metformin hydrochloride Tablets contain

- The active substance is metformin (as hydrochloride). Each prolonged release tablet contains 500 mg, 750 mg or 1000 mg of metformin hydrochloride corresponding to 390 mg, 585 mg and 780 mg metformin base, respectively.
- The other ingredients are magnesium stearate, colloidal anhydrous silica, povidone K30 and hypromellose.

What Metformin hydrochloride Tablets looks like and contents of the pack

Metformin hydrochloride 500 mg prolonged release tablets are white to off-white, capsule shaped uncoated tablets, 16.50 mm in length, 8.20 mm in width, debossed with 'XR500' on one side and plain on other side.

Metformin hydrochloride 750 mg prolonged release tablets are white to off-white, capsule shaped, uncoated tablets, 19.60 mm in length, 9.30 mm in width, debossed with 'XR 750' on one side and plain on other side. Metformin hydrochloride 1000 mg prolonged release tablets are white to off-white, capsule shaped, uncoated tablets, 21.10 mm in length, 10.10 mm in width, debossed with 'XR 1000' on one side and plain on other side.

Metformin hydrochloride Tablets is available in blister packs containing 14, 20, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 180, 600 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer

Strides Pharma UK Ltd.
Unit 4, The Metro Centre,
Dwight Road, Watford
WD18 9SS
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

- Denmark – LYOMET
 - Hungary – Tardemet XR 500,750,1000 mg Retard tableta
 - Poland – LYOMET SR
 - Czech Republic – GLUCOMET
 - United Kingdom (Northern Ireland) – Metformin hydrochloride 500 mg,750 mg,1000 mg Prolonged – release Tablets
 - Slovak Republic – Metformin Mylan XR 500 mg, 750 mg, 1000 mg tablety s predĺženým
- This leaflet was last revised in 09/2021

9804

140 x 490 mm

Front Side

140 x 490 mm

Back Side



P086

1046710

Fonts used : Times New Roman
Font Size : Min. 9 pt., Max. 14 pt.,

ARTWORK DETAIL LABEL

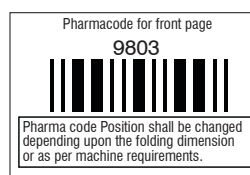
Non Printing Colour

Product	Metformin hydrochloride 500 mg, 750 mg, 1000 mg prolonged release tablets			
Buyer/Country	Strides Pharma UK Ltd. / UK	Component	Pack Insert	
Dimension	140 x 490 mm	Pack	NA	
New Item Code	1046710	Old Item Code	1038714	
Colour Shades	Black	No. of Colours	1	

Change Control No.	PC-TSG/2020/482 - Record Number: 277470	Artwork Version	3.1
Design/Style	Front & Back Printing, to be supplied in folded size of 140 x 31mm		
Substrate	60 GSM paper		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	NA		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

RD/PD/003/F-08/R0



Pharmacode for front page
9803

Pharma code Position shall be changed depending upon the folding dimension or as per machine requirements.