

GLYCOMET – 500 SR (Metformin Hydrochloride Sustained Release Tablets)

Metformin Hydrochloride (500 mg)

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What Glycomet - 500 SR is used for

Treatment of type 2 diabetes mellitus in adults, when dietary management and exercise alone does not result in adequate glycaemic control. Metformin extended release may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.

How Glycomet - 500 SR works

Metformin belong to a group of drugs called biguanide that prevents high blood sugar levels by lowering blood sugar levels in the fasting state and following a meal. It does not stimulate insulin secretion and therefore does not produce low blood sugar levels.

Before you use Glycomet - 500 SR

- When you must not use it

- If you are allergic to metformin
- have ketoacidosis (this is a symptom of uncontrolled diabetes in which substances called 'ketone bodies' accumulate in the blood – you may notice that your breath has an unusual, fruity odour)
- have long term kidney or liver problems,
- have had serious complications with your diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or dehydration,
- have been treated for heart problems or have recently had a heart attack or

have severe circulatory problems or breathing difficulties.

Do not take Glycomet – 500 SR:

- If you have severely reduced kidney function.
- If you have lactic acidosis [too much lactic acid in the blood (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 of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).

- Before you start to use it

If you need to have an X-ray examination involving the injection of a dye, tell the doctor that you take Glycomet-500 SR as you may need to stop taking it for a few days afterwards.

Tell your doctor if you are going to have an operation under general anaesthetic, as you may need to stop taking Glycomet-500 SR for a couple of days before and after the procedure.

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.

Take special care with Glycomet-500 SR

Risk of lactic acidosis

Glycomet – 500 SR 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, 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 Glycomet – 500 SR 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

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

During treatment with Glycomet – 500 SR, 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 functions.

- Before you start to use it

If any of the above applies to you, talk to your doctor before you start taking this medicine.

Pregnancy and breast-feeding

Do not take Glycomet – 500 SR tablets if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

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

If you are taking any of the following medicines, your blood sugar levels may need to be checked more often and your dose adjusted:

- Glucocorticoids (systemic and local routes)
- Beta-2-agonists
- Diuretics

How to use Glycomet - 500 SR

- How much to use

The usual starting dose is one tablet once daily.

Dosage increases should be made in increments of 500mg every 10-15 days based on your blood sugar level, up to a maximum of 2000mg once daily with the evening meal.

In patients already treated with metformin tablets, the starting dose of Metformin sustained release tablets should be equivalent to the daily dose of metformin immediate release tablets.

Always take Glycomet – 500 SR tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor may prescribe Glycomet – 500 SR tablets to take alone, or in combination with other oral antidiabetic medicine or insulin.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Glycomet - 500 SR Tablet for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you take extra tablets by mistake you need not worry, but if you have unusual symptoms, contact your doctor. If the overdose is large, lactic acidosis (too much acid in the body due to the buildup of lactic acid in the body. Lactic acidosis occurs when cells make lactic acid (from glucose) faster than it can be broken down. The key signs of lactic acidosis include unusually deep and rapid breathing, vomiting, and abdominal pain) is more likely and this is a medical

emergency requiring treatment in hospital.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking Glycomet - 500 SR Tablet.

If you have diabetes you should have your blood or your urine tested for sugar regularly. You should return to your doctor at least once a year to check the function of your kidneys (more often if you are elderly or if you have kidney problems).

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

You should avoid drinking alcohol and using alcohol-containing medicines as this will increase the risk of lactic acidosis.

- Things to be careful of

Driving and using machines

Glycomet – 500 SR taken on its own do not cause ‘hypos’ (symptoms of low blood sugar or hypoglycaemia, 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 Glycomet - 500 SR taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any of the following, stop taking Glycomet-500 SR and see your doctor immediately:

- unexpected weight loss
- very severe nausea or vomiting

- very fast breathing which you cannot stop

- stomach pains or feeling cold

These can be signs of serious problems with your diabetes and may mean you have a very rare side effect called “lactic acidosis” (too much acid in the blood). If this happens, see a doctor as you will need treatment straight away.

Other possible side effects are listed by frequency as follows:

Very common side effects (may affect more than 1 in 10 people):

- Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. These undesirable effects occur most frequently during initiation of therapy and resolve spontaneously in most cases.

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

- Taste disturbance
- Decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

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

- Skin rashes including redness, itching and hives.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Glycomet - 500 SR

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Off- white coloured, oval biconvex, film coated tablets plain on both sides.

- Ingredients

- Active ingredient

Metformin Hydrochloride.

- Inactive ingredients

Stearic acid, shellac (refined bleached), Povidone K-30, silica colloidal anhydrous, magnesium stearate, Hypromellose (E15 Premium/2910), hydroxy propyl cellulose, titanium dioxide, propylene glycol, macrogol 6000 and talc.

- MAL number:

MAL15105035AZ

Manufacturer

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Product Registration Holder

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