

Glycomet-500/850/1000 (Metformin Tablets BP 500/850/1000mg)

Metformin Hydrochloride 500 mg / 850 mg / 1000 mg

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What Glycomet Tablet is used for

Glycomet tablets contain the active ingredient metformin hydrochloride. Metformin hydrochloride belongs to a group of medicines called biguanides used for the treatment of non-insulin-dependent diabetes mellitus (type 2 diabetes) in adults and children from 10 years of age.

Glycomet tablets are a medicine used to lower high blood sugar levels in patients with diabetes mellitus (type 2 diabetes); particularly in overweight patients when dietary management and exercise alone does not result in control of blood sugar.

How Glycomet Tablet works

Insulin is a hormone produced by the pancreas that makes your body take in glucose (sugar) from the blood. Your body uses glucose to produce energy or stores it for future use.

If you have diabetes, your pancreas does not make enough insulin or your body is not able to use properly the insulin it produces. This leads to a high level of glucose in your blood. Metformin helps to lower your blood glucose to as normal a level as possible.

Before you use Glycomet Tablets

- When you must not use it

- if you are **allergic (hypersensitive)** to metformin hydrochloride or any of the other ingredients of Glycomet tablets.
- if you have uncontrolled diabetes, e.g. severe hyperglycaemia (very high levels of glucose in the blood) or ketoacidosis. Ketoacidosis is a state of

health, where substances called 'ketone bodies' accumulate in the blood. Symptoms include stomach pain, fast and deep breathing, sleepiness or unusual fruity odour of the breath

- if you have kidney problems.
- if your kidney function worsens as a consequence of e.g. loss of too much water (dehydration) due to long-lasting vomiting or severe diarrhoea. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis.

• If you have a severe infection, such as infection affecting your lung or bronchial system or your kidney. Severe infection may lead to kidney problems, which can put you at risk for lactic acidosis.

- if you have acute or chronic diseases which may lead to reduced amount of oxygen in body tissues (tissue hypoxia) such as

- heart failure, or difficulties breathing
- recent heart attack (myocardial infarction)

- collapse or trauma (shock)

- if you have liver problems, drink a lot of alcohol or suffer from alcoholism

- if you are breast-feeding.

Do not take Glycomet Tablets:

- 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

Risk of lactic acidosis

Glycomet 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, 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 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 Glycomet 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

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

During treatment with Glycomet 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 functions.

Normal kidney function is essential for treatment with Glycomet tablets because of the risk of developing hyperacidity of the blood. This is due to accumulation of lactic acid (lactic acidosis) and is mainly determined by your kidney function. Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this happens to you, you may need immediate treatment. Stop

taking Metformin immediately and tell your doctor straight away.

Metformin in itself does not lead to hypoglycaemia (insufficient level of blood sugar), but if you take Metformin with other medicaments for the treatment of diabetes, which can cause hypoglycaemia (e.g. sulfonylureas, insulin) there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, visions disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

- Taking other medicines

If you need to have an injection of contrast medicines that contain iodine into your bloodstream, for example for examinations such as X-ray or scan, you must stop taking Metformin for a certain period of time before and after the examination.

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

During maintenance therapy with Glycomet tablets starting or stopping any other medicinal therapy can interfere with your blood sugar control.

Please especially inform your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- corticosteroids (e.g. prednisone)
- specific medicines for the treatment of high blood pressure (ACE inhibitors, e.g. captopril, enalapril)
- medicines which increase urine production (diuretics, e.g. furosemide)
- specific medicines for the treatment of bronchial asthma (β -agonists, e.g. salbutamol)
- iodinated contrast agents
- medicines containing alcohol.

How to use Glycomet Tablets

- How much to use

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

Metformin 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. The dose of Glycomet tablets should be determined by the doctor according to your blood sugar levels.

Unless prescribed differently by your doctor, the usual dose is:

Dosage for adults

The usual starting dose is 500 mg or 850mg metformin hydrochloride, two or three times a day. The maximum daily dose is 3000 mg metformin hydrochloride, taken as 3 divided doses.

Dosage for children from 10 years of age and adolescents:

The usual starting dose is 500 mg or 850 mg metformin hydrochloride once a day.

The dosage can be increased up to the maximum recommended daily dose of 2000 mg metformin hydrochloride per day, taken as 2 or 3 divided doses. Treatment of children between 10 and 12 years of age is only recommended on specific advice from your doctor, as experience in this age group is limited.

- When to use it

Take the tablets during or after meals with an adequate amount of liquid. Do not chew the tablets. When taking 2 or more doses you should spread them out over the day, e.g. 1 dose each during or after breakfast and dinner.

Talk to your doctor if you think the dose of Glycomet tablets are too high or too low.

- How long to use it

Your doctor will adapt your dose of Metformin to your blood glucose levels. Make sure that you talk to your doctor regularly. This is particularly important for children and adolescents or if you are an older person.

- If you forget to use it

If you forget to take Glycomet tablets, take the prescribed amount of Glycomet tablets at the next prescribed time and try to keep to the prescription in future. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Inform your doctor immediately if you have taken more tablets than you should have. An overdose of Glycomet tablets

does not lead to hypoglycaemia but increases the risk of hyperacidity of the blood caused by lactic acid (lactic acidosis). Symptoms of early hyperacidity are similar to the side effects of metformin on the gastrointestinal tract: sickness, vomiting, diarrhoea and abdominal pain. In severe cases you could also get muscle pain and muscle cramps, very fast breathing which you cannot stop, as well as a clouding of consciousness and coma. This may develop within hours and requires immediate emergency treatment in a hospital.

While you are using it

- Things you must do

Metformin hydrochloride may cause a very rare, but serious complication called lactic acidosis, particularly if your kidneys are not working properly.

If this happens to you, you may need immediate treatment. Stop taking Glycomet tablets immediately and tell your doctor straight away.

Metformin hydrochloride on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin hydrochloride together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, glinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, visions disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

- Things you must not do

Taking Glycomet tablets with food and drink

Drinking alcohol whilst being treated with Glycomet tablets increases the possibility of hypoglycaemia (low blood sugar levels) and lactic acidosis. Therefore, you should avoid consumption of alcohol while you are taking Metformin.

Pregnancy and breast-feeding

Diabetic women who are pregnant or planning to become pregnant, should not be treated with Glycomet tablets. Instead, insulin should be used to maintain blood glucose levels as close to normal as possible. Inform your doctor if you are pregnant or thinking of becoming

pregnant so that he or she can change you to insulin therapy.

This medicinal product should not be used while breast-feeding.

- Things to be careful of

Ask your doctor for advice before taking Metformin if any of the following conditions apply to you:

- undergoing surgery under general anaesthetic
- overweight
- using other medicines

It is important to do the following regularly:

- consult your prescribing doctor particularly at the beginning of Metformin treatment
- usual blood and urine laboratory tests to manage your diabetes
- kidney function checks by your doctor at least once a year
- People 65 years or older and people just within normal kidney function need these checks at least two to four times a year.
- eat meals regularly throughout the day when using Metformin

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur:

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

- digestive problems, such as feeling sick (nausea), being sick (vomiting), diarrhoea, bellyache (abdominal pain) and loss of appetite. These side effects most often happen at the beginning of the treatment with Glycomet. It helps if you spread the doses over the day and if you take Glycomet with or straight after a meal. If symptoms continue, stop taking Glycomet and talk to your doctor.

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

- changes in taste.
- 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)

- lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly.
- Symptoms of lactic acidosis are vomiting, stomach-ache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking Glycomet immediately and contact a doctor or the nearest hospital straight away.
- Lactic acidosis is a medical emergency and must be treated in a hospital.
- 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). If this happens to you, stop taking Glycomet and talk to your doctor.
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).

Limited data in children and adolescents showed that adverse events were similar in nature and severity to those reported in adults.

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 nprra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Glycomet Tablets

- Storage

Keep out of the reach of children.

Do not use Glycomet Tablets after the expiry date, which is stated on the carton and on the blister after EXP.

Store below 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

Glycomet-500 mg tablets are supplied as White to off white, round, biconvex, film coated tablets plain on both sides.

Glycomet-850 mg tablets are supplied as white to off white capsule shaped, biconvex, film coated tablets with scoreline on one side and plain on other side.

Glycomet-1000 mg tablets are supplied as white to off white oval shaped, biconvex, film coated tablets, deep breakline on one side and breakline on other side.

- Ingredients

-Active ingredient:
Metformin Hydrochloride.

Each film-coated tablet contains Metformin Hydrochloride Ph. Eur. 500 mg / 850 mg / 1000 mg.

-Inactive ingredients:

Tablet core : Sodium Starch Glycolate (Type A), Povidone K-30, Maize Starch, Silica Colloidal Anhydrous, Magnesium Stearate,.

Tablet coating: Opadry White 04G58897 (consisting of Hypromellose 15cP, Talc, Titanium Dioxide, Macrogol 6000, Propylene Glycol)

- MAL number(s):

Glycomet-500 mg tablets:
MAL16075023AZ

Glycomet-850 mg tablets:
MAL16075020AZ

Glycomet-1000 mg tablets:
MAL16075022AZ

Manufacturer

USV Private Limited
H-13,16,16A,17,18,19,20,21,E-22,
O.I.D.C., Mahatma Gandhi Udyog Nagar,
Dabhel, Daman – 396210, India.

Product Registration Holder

Medispec (M) Sdn Bhd
No. 55 & 57, Lorong Sempadan 2
(off Boundary Road)
11400 Ayer Itam, Penang

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