

GLUCOMET™ TABLET 500MG

Metformin Hydrochloride 500 mg

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What GLUCOMET™ TABLET 500MG is used for

GLUCOMET™ TABLET 500MG is used for the treatment of type 2 diabetes mellitus in adult, when dietary management and exercise alone does not result in adequate glycemic control.

GLUCOMET™ TABLET 500MG may be used as alone or in combination with other oral antidiabetic agents, or with insulin.

In type 1 diabetes, GLUCOMET™ TABLET 500MG may be given as an adjuvant to patients whose symptoms are poorly controlled.

How GLUCOMET™ TABLET 500MG works

Metformin belongs to a group of medicines called biguanides (a type of medication which lowers blood glucose level).

In type 2 diabetes, there is too much sugar (glucose) in blood. This is because the body does not make enough insulin or because it makes insulin that does not work properly. Insulin is a hormone that allows your body tissue to take glucose from the blood and use it for energy or for storage for future use.

GLUCOMET™ TABLET 500MG works by:

- reducing glucose production in the liver
- increasing insulin sensitivity in muscle and improving peripheral glucose uptake and utilization
- decreases intestinal glucose absorption

GLUCOMET™ TABLET 500MG improves the sensitivity of body to insulin. It helps the body to use glucose in the normal way.

In patients who are overweight, long-term use of GLUCOMET™ TABLET 500MG also helps to lower the risk of any problems related to diabetes.

Before you use GLUCOMET™ TABLET 500MG

- When you must not use it

Do not take GLUCOMET™ TABLET 500MG

- if you have known hypersensitivity (allergic) to Metformin or any other ingredients in this medicine
- 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)
- if you have recently had a heart attack or any other heart problems
- if you have severe circulation problems or difficulty in breathing
- if you have liver problems or are a heavy drinker of alcohol
- if you have severely reduced kidney function
- if you have any acute condition with the potential to alter

kidney function such as dehydration, severe infection or injury or trauma (shock)

- if you have acute or chronic disease which may cause deficiency of oxygen in tissue (tissue hypoxia) such as circulation problems or difficulty in breathing (cardiac or respiratory failure), recent heart attack and shock
- if you are pregnant, planning to get pregnant or are breastfeeding.

- Before you start to use it

Take special care and check with your doctor or pharmacist before taking GLUCOMET™ TABLET 500MG if:

- you are elderly
- you are on a very low calorie diet (less than 1000 calories a day) or are fasting. This could increase the chances of you getting a very rare, but serious side effect called lactic acidosis.

Risk of lactic acidosis:

GLUCOMET™ TABLET 500MG 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 GLUCOMET™ TABLET 500MG for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhea,

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fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking GLUCOMET™ TABLET 500MG 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 includes:

- 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 GLUCOMET™ TABLET 500MG, 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.

Tell doctor or pharmacist if you are allergic to any medicines or if have any other medical conditions. Please inform doctor or pharmacist if you are pregnant or lactating.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medications, including cimetidine and anticoagulant. This is because metformin can affect the way some other medications work. Also, some medications can affect the way Metformin works.

GLUCOMET™ TABLET 500MG on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take GLUCOMET™ TABLET 500MG together with other

medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, 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.

Do not drink alcohol or take medicines containing alcohol while taking GLUCOMET™ TABLET 500MG.

How to use GLUCOMET™ TABLET 500MG

Always take GLUCOMET™ TABLET 500MG exactly as directed by doctor or pharmacist. Check with doctor or pharmacist if you are not sure.

- How much to use

Adult: One tablet of GLUCOMET™ TABLET 500MG is usually taken, three times daily. The daily maximum dose is 3g.

- When to use it

Take GLUCOMET™ TABLET 500MG with or after a meal. This will avoid you having side effects affecting your digestion. GLUCOMET™ TABLET 500MG should be taken at the same time daily. Swallow tablet with a glass of water.

- How long to use it

GLUCOMET™ TABLET 500MG should be taken regularly and as long as your doctor advised.

- If you forget to use it

If you miss a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. Do not take two doses at once.

- If you use too much (overdose)

If you take too many tablets, contact your doctor immediately or go to the nearest hospital emergency department.

If you have taken more GLUCOMET™ TABLET 500MG than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are vomiting, abdominal pain with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Hypoglycemia may also occur when Metformin is given concomitantly with a sulfonylurea, insulin or alcohol. Intensive supportive therapy which should be particularly directed at correcting fluid loss and metabolic disturbance is recommended.

While you are using GLUCOMET™ TABLET 500MG

- Things you must do

- Have a regular monitoring of renal function
- Have an annual estimation of Vitamin B12 levels
- Have a regular blood glucose level monitoring.

Pregnancy / Breast-feeding / Lactation

You must tell your doctor if you think you are (or might become) pregnant. During pregnancy, you need insulin to treat your diabetes. Tell your doctor if you are, you think you might be or are planning to become pregnant, so that he or she may change your treatment. This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

- Things you must not do

Do not drink alcohol when you take this medicine. Alcohol may increase the risk of lactic acidosis especially if you have liver problems or if you

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are undernourished. This also applies to medicines that contain alcohol.

Do not start taking this medicine or change the dosage without first checking with your doctor. Do not give this medicine to anyone else, even if their symptoms or conditions seem similar to yours. Do not stop taking GLUCOMET™ TABLET 500MG, or change the dosage, without checking with your doctor

- Things to be careful of

Driving and using machines

GLUCOMET™ TABLET 500MG on its own does not usually affect your ability to drive. However, take special care if you take GLUCOMET™ TABLET 500MG together with other medicines to treat diabetes that can cause hypoglycaemia. Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

Side effects

Like all medicines, GLUCOMET™ TABLET 500MG can cause side effects, although not everybody gets them. The following side effects may occur:

- hypoglycaemia. If you are taking GLUCOMET™ TABLET 500MG together with other medicines such as sulfonylurea, hypoglycaemia may occur, therefore blood glucose should be monitored.
- Common side effects (may affect up to 1 in 10 people): 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.

- metallic taste in the mouth
- epigastric discomfort
- nausea and vomiting
- lactic acidosis, rarely diarrhea and
- anorexia (loss of appetite).

Most of these reactions are transient and can be controlled by reducing the dosage or by discontinuing therapy.

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

Storage and Disposal of

GLUCOMET™ TABLET 500MG

- Storage

Store at temperature below 30°C.

Keep out of the reach and sight of children.

Do not use GLUCOMET™ TABLET 500MG after the expiry (EXP) date which is stated on the carton and on the blister. The expiry date refers to the last day of that month.

- Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product Description

- What it looks like

GLUCOMET™ TABLET 500MG is white to off-white round tablet, one side impressed with a score and the other side with a mark: “”.

- Ingredients

- Active ingredient
Metformin Hydrochloride

- Inactive ingredients
Polyethylene Glycol
Silicon Dioxide
Magnesium Aluminium Silicate
Magnesium Stearate
Sodium Lauryl Sulfate
Cellulose

- MAL number:

MAL 20040950AZ

Manufacturer and Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd.
Lot 3, 5, 7 & 12, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru
Bangi, 43000 Kajang, Selangor,
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