

ORALMET[®] TABLET

Metformin Hydrochloride (500mg, 850mg and 1000mg)

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What Oralmet[®] Tablet is used for

Oralmet[®] is used to treat patients with type 2 diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients. Adults can take Oralmet[®] on its own or together with medicines to treat diabetes (medicines taken by mouth or insulin).

Children 10 years and over and adolescents can take Oralmet[®] on its own or together with insulin.

How Oralmet[®] 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. Oralmet[®] helps to lower your blood glucose to as normal level as possible.

If you are an overweight adult, taking Oralmet[®] over a long period of time also helps to lower the risk of complications associated with diabetes. Oralmet[®] is associated with either a stable body weight or modest weight loss.

Before you use Oralmet[®] Tablet

When you must not use it

Do not take Oralmet[®]

- If you are allergic (hypersensitive) to metformin or any of the other ingredients of this medicine.
- 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-come. Symptoms of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).
- If you have uncontrolled diabetes, with e.g. severe hyperglycaemia (high blood glucose), nausea, vomiting, dehydration, rapid weight loss or ketoacidosis.
- If you 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
- If you have a severe infection, such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis
- If you are treated for heart failure or have recently had a heart attack, have severe problems with your circulation (such as shock) or have breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis
- If you drink a lot of alcohol

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

Risk of lactic acidosis

Oralmet[®] Tablet 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 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 Oralmet[®] Tablet for a short time if you have a condition that may be associated with dehydration (significant loss of body fluid) 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 Oralmet[®] Tablet 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

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

Before you start to use it

During treatment with Oralmet[®], your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have a worsening kidney function.

Talk to your doctor or pharmacist before taking Oralmet[®] if:

- you need to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your blood stream.
- you need to have major surgery. You must stop taking Oralmet[®] for a certain period of time before and after the examination or the surgery. Your doctor will decide when you must stop and when to restart your treatment with Oralmet[®]. It is important that you follow your doctor's instruction precisely.

Take special care with Oralmet[®]

Oralmet[®] on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Oralmet[®] 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, 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 Oralmet[®] for a certain

period of time before and after the examination. Your doctor will decide when you must stop and when to start your treatment with Oralmet[®].

Tell your doctor if you take any of the following medicines and Oralmet[®] at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of Oralmet[®]:

- Organic cation transporter (co-administration of metformin with verapamil, rifampicin or cimetidine may affect the levels of metformin)
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure
- Medicinal products which affects kidney function such as Diuretics (used to remove water from the body by making more urine), NSAIDs (used in pain relief), ACE inhibitors (reduces blood pressure)
- Glucocorticoid (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma)
- Other medicines used to treat diabetes

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

How to use Oralmet[®] Tablet

- How much to use

- Paediatric population usually start with 500mg or 850mg Oralmet[®] once a day. The maximum daily dose is 2000 mg taken as 2 or 3 divided doses. Oralmet[®] can be used in children from 10 years of age and adolescents.
- Adults with normal renal function (GFR $\geq$ 90 mL/min) usually start with 500mg or 850mg Oralmet[®] two or three

times a day. The maximum recommended dose of metformin hydrochloride is 3g daily, taken as 3 divided doses.

- If you take insulin too, your doctor will tell you how to start Oralmet[®]. Patient without renal impairment (stage 2). Max: 3,000 mg daily in 2-3 divided dose, (stage 3a) Max: 2,000 mg daily on 2-3 divided dose, (stage 3b) Max: 1,000 mg daily in 2-3 divided doses.
- If after some time, you think that the effect of Oralmet[®] is too strong or too weak, talk to your doctor or pharmacist.

- When to use it

Oralmet[®] can be taken with or after meals.

- How long to use it

Refer to your pharmacist or doctor for advice

- If you forget to use it

Consult your doctor or pharmacist on what you should do 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)

High overdose of metformin may lead to lactic acidosis. Lactic acidosis is a medical emergency and must be treated in hospital.

While you are using it

- Things you must do

Check your diabetic level regularly. Remember to continue your diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy restricted diet.

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- Things you must not do

Taking Oralmet[®] with food and drink:

Do not drink alcohol when you take this medicine. Alcohol may increase the risk of lactic acidosis especially if you have liver problems, are fasting or if you are undernourished. This also applies to medicines that contain alcohol.

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to. Do not give this medicine to anyone else, even if they have the same condition as you. Do not stop taking Oralmet[®], or change the dosage, without checking with your doctor.

- Things to be careful of

It is important to maintain blood glucose levels as close to normal as possible throughout pregnancy, to reduce the risk of adverse hyperglycaemia outcomes to the mother and her child.

Speak to your doctor in case any changes will be needed to your treatment or monitoring of your blood glucose levels.

This medicine is not recommended if you are breastfeeding or if you are planning to breastfeed your baby.

Driving and using machines

Oralmet[®] on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines.

Side effects

Like all medicines, Oralmet[®] can cause side effects, although not everybody gets them.

Some side effects could be serious. Tell your doctor straight away if you have any of the following side effects:

Very common side effects:

- 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 Oralmet[®]. It helps if you spread the doses over the day and if you take Oralmet[®] with or straight after a meal. If symptom continue, stop taking Oralmet[®] and talk to your doctor.

Common side effects:

- 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:

- lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly.
- Symptoms of lactic acidosis are vomiting, stomachache (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 Oralmet[®] 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 white of the eyes). If this happens to you, stop taking Oralmet[®] 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.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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 Oralmet[®] Tablet

- Storage

Store in a cool dry place at below 30°C, protect from direct light and humidity.

- Disposal

The expiry date of Oralmet[®] is printed on the carton and blister. Do not use if after expiry date.

Medicines should not be disposed of via wastewater or household waste. If your doctor tells you to stop taking Oralmet[®] or the expiry date has passed, ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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Product Description

- What it looks like

Oralmet[®] Tablet 500mg

White or off-white, round convex, film-coated, 12mm in diameter tablet, inscribed with 'SL' logo on one side and score line on the other.

Date of revision

17/04/2024

Serial number

NPRA (RX) XX/XXX

Oralmet[®] Tablet 850mg

Off-white to slightly yellow, film-coated tablet, 14mm in diameter, convex inscribed with 'SL' logo on one side and plain on the other.

Oralmet[®] Tablet 1000mg

White or off-white, film coated tablet, capsule shaped 10 x 18.75 mm with score line one side and "SL 1G" logo on the other.

- Ingredients

Active ingredient:

Metformin Hydrochloride BP

Inactive ingredients:

Povidone

Macrogol

Sorbitol

Magnesium stearate

Paraffin

Opadry White

Purified Water

- MAL Number

Oralmet[®] Tablet 500mg

(MAL19913428ACZ)

Oralmet[®] Tablet 850mg

(MAL08111760ACZ)

Oralmet[®] Tablet 1000mg

(MAL08091387ACZ)

Manufacturer

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