

AURO METFORMIN

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

Consumer Medication Information Leaflet (RiMUP)

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What is AURO METFORMIN used for

Treatment of Type 2 Diabetes Mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glucose level (glycaemia) control.

In adults, AURO METFORMIN may be used as alone or in combination with other oral anti-diabetic agents or with insulin.

In children from 10 years of age and adolescents, AURO METFORMIN may be used as alone or in combination with insulin.

A reduction of diabetic complications has been shown in overweight Type 2 diabetic adult patients treated with AURO METFORMIN as first-line therapy after diet failure.

How AURO METFORMIN works

AURO METFORMIN belongs to a group of medicines called biguanides which act by lowering blood plasma glucose (i.e. anti-hyperglycaemic effect) during both i.e before & after taking food (basal and postprandial). It does not stimulate insulin secretion and therefore does not decrease the blood glucose level (hypoglycaemia).

Before you use AURO METFORMIN

-When you must not use it

Do not take AURO METFORMIN:

- If you have allergic (hypersensitivity) to metformin hydrochloride or to any of the excipients
- If you have shortage of insulin (diabetic ketoacidosis), diabetes related to decreased glucose level (diabetic pre-coma)
- If you have severely reduced kidney function
- If you have lactic acidosis [too much lactic acid in the blood (see "Risk of lactic acidosis")] 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 acute or chronic disease which may cause decrease in oxygen supply to the tissue (tissue hypoxia) such as:
 - cardiac or respiratory failure
 - recent interruption to the heart (myocardial infarction)
 - shock
- If you have liver (hepatic) insufficiency, acute alcohol intoxication, alcoholism
- Lactation

-Before you start to use it

Before taking this medicine, you should get your doctor know if you are pregnant or breast-feeding or wish to become pregnant or start breast-feeding.

Metformin tablets 500mg contains 19.3mmol (or 0.84mg) sodium per tablet and Metformin tablets 850 mg contains 32.8mmol (or 1.4mg) sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.

If you are already on insulin you should only be started on a course of treatment with metformin tablets in hospital. Metformin is not

recommended in patients below the age of 10 years.

You should not drink alcohol whilst you are taking metformin tablets.

Risk of lactic acidosis

AURO METFORMIN 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 AURO METFORMIN 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 AURO METFORMIN 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 AURO METFORMIN 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.

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-Taking other medications

If you need to have an injection of contrast medicines that contain iodine in 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. This is because metformin can affect the way some other medicines work. Also, some medicines can affect the way metformin works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines as you may need more frequent blood glucose tests or your doctor may adjust the dosage of metformin:

- Medicines of high blood pressure (hypertension) such as water tablets (diuretics), ACE Inhibitors (such as enalapril)
- Beta-2 agonists such as salbutamol (used to treat asthma)
- Glucocorticoids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma)
- Other medicines used to treat diabetes

Taking metformin 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 or if you are undernourished.

How to use AURO METFORMIN

-How much to use

Always take metformin exactly as your doctor has told you. 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.

Usual dose:

Children 10 years and over and adolescents usually start with 500mg or 850mg metformin once a day. The maximum daily dose is 2000mg taken as 2 or 3 divided doses.

Adults usually start with 500mg or 850mg metformin two or three times a day. The maximum daily dose is 3000mg taken as 3 divided doses.

If you take insulin too, your doctor will tell you how to start metformin.

-When to use it

Take tablets exactly as directed by your doctor or pharmacist. Take the tablets with or after a meal. This will avoid you having side effects affecting your digestion.

Do not crush or chew the tablets. Swallow each tablet with a glass of water.

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

-How long to use it

Keep taking AURO METFORMIN until the treatment is finished, even if you feel better do not stop taking the tablets. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

-If you forget to use it

Take a missed dose as soon as you remember. However if it is too close to the next dose, omit the missed dose and return to your normal dosing schedule. Do not double a dose under any circumstances.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

-If you use too much (overdose)

If you have taken more Metformin than you should have, talk to your doctor or go to the nearest hospital.

While you are using it

-Things you must do

If you feel unwell or if you have concerns about a side effect, you will need to seek advice. If you feel very ill, get medical help straight away. If you have any unused medicine, return it to your pharmacist who will dispose of it safely. These measures will help to protect the environment.

All patients should continue their diet with regular distribution of carbohydrates intake during the day. Overweight patients should continue their energy restricted diet.

The usual laboratory tests for diabetes monitoring should be performed regularly.

-Things you must not do

You must not take the medicine after the expiry date shown on the packaging.

-Things to be careful of

AURO METFORMIN may cause a very rare, but serious complication called lactic acidosis, particularly if your kidneys are not working properly. 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 AURO METFORMIN immediately and tell your doctor straight away.

Side effects

The following undesirable effects may occur under treatment with Metformin.

Nervous System Disorders
Common: Taste disturbance

Gastrointestinal Disorders
Very common: Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite.

These undesirable effects occur most frequently during initiation of

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therapy and resolve spontaneously in most cases. To prevent them, it is recommended that Metformin be taken in 2 to 3 daily doses during or after meals. A slow increase of the dose may also improve gastrointestinal tolerability.

Please inform your doctor or pharmacist if you experience any undesirable effects.

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 AURO METFORMIN

-Storage

Keep out of the reach and sight of children. Store below 30°C.

Do not use AURO METFORMIN after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.

-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

AURO METFORMIN 500: White, biconvex, circular shaped film coated tablets, debossed with 'A' on one side and '60' debossed on the other side.

AURO METFORMIN 850: White, biconvex, circular shaped film coated tablets, debossed with 'A' on one side and '61' debossed on the other side.

AURO METFORMIN 1000: White biconvex, oval shaped, film coated tablets with a score line in between '6' and '2' on one side and 'A' debossed on the other side.

-Ingredients

- Active ingredient(s)
Metformin Hydrochloride
- Inactive ingredient(s)
AURO METFORMIN 500:
Povidone, Magnesium stearate, Hypromellose, PEG 400/Macrogol 400, PEG 6000/Macrogol 6000

AURO METFORMIN 850:
Povidone, Magnesium stearate, Hypromellose, Polyethylene glycol 400, Polyethylene glycol 6000

AURO METFORMIN 1000: Povidone, Magnesium stearate, Hypromellose, PEG 400/Macrogol 400, PEG 6000/Macrogol 6000

-MAL number

AURO METFORMIN 500
MAL12065080AZ

AURO METFORMIN 850
MAL14075074AZ

AURO METFORMIN 1000
MAL12065081AZ

Manufacturer

Aurobindo Pharma Limited
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Product Registration Holder

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-09/03/2020

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