

METTA SR TABLET

Metformin Hydrochloride (500 mg, 750 mg)

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What Metta SR is used for

Metformin is used for the treatment of Type 2 (non-insulin dependent) diabetes mellitus when diet and exercise changes alone have not been enough to control blood glucose (sugar).

How Metta SR works

Metformin is an antihyperglycemic agent (lowering glucose levels in the blood). People with Type 2 diabetes do not make enough insulin in their pancreas or their body does not respond properly to the insulin it does make. This causes a build-up of glucose in the blood which can cause a number of serious long-term problems. Metformin SR makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Before you use Metta SR

- When you must not use it

Do not take Metta SR if you:

- Have long-term kidney or liver problems.
- Have been treated for heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties.
- Are allergic to metformin or to any of the other ingredients.
- Have ketosis (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 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).

Pregnancy and lactation

Do not take Metta SR if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Metta SR if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Tell your doctor if you:

- Have kidney problem which may cause lactic acidosis (low pH in body tissue and blood).
- Have deficiency of vitamin B12 and folic acid.
- You have or have had any medical conditions, especially the following:
 - Hypoxia such as sepsis, dehydration.
 - Heart or blood vessel problems, including heart failure.
 - Seizures or alcohol dependence.

Risk of lactic acidosis

Metta 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 Metta SR 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 Metta 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 Metta 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 function.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Alcohol, barbiturates, salicylate and phenothiazines may precipitate lactic acidosis. Alcohol may precipitate hypoglycemia, as could sulfonylureas given in combination with Metformin. If you are taking any of the following medicines, your blood sugar levels may need to be checked more often and your dose adjusted:

- Diuretics (water tablets) such as furosemide.
- Calcium channel blocker such as Nifedipine may enhance the absorption of Metformin.

How to use Metta SR

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help. Monotherapy and combination with other oral antidiabetic agents: Usual starting dose: 1 tab once daily.

The maximum recommended doses for the 500mg and 750mg tabs are 4 and 2 tabs/day, respectively.

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Elderly: Due to the potential for decreased renal function in elderly subjects, the Metformin dosage should be adjusted based on renal function. Regular assessment of renal function is necessary.

Children: In the absence of available data, Metformin should not be used in children

- When to use it

Should be taken with food (Take with evening meals. Swallow whole, do not chew/ crush).

- How long to use it

Continue taking Metta SR 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)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- If you need to have an X-ray examination involving the injection of a dye, tell the doctor that you take Metta 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 Metta SR for a couple of days before and after the procedure.
- Take your medicine exactly as your doctor has told you.
- 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.

- Do not give Metformin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

You may see some remains of the tablets in your stools. Do not worry- this is normal for this type of tablet.

Side effects

Like all medicines, Metformin can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

The most severe side effect associated with Metformin is lactic acidosis.

- Early symptoms of lactic acidosis may be nonspecific consisting of:
 - Nausea.
 - Vomiting.
 - Abdominal pain.
 - Diarrhoea.
- Other reactions include:
 - Megaloblastic anemia.
 - GI symptoms (diarrhea, vomiting etc).
 - Sensitivity reactions such as rash, urticaria and pruritis may occur.
- 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 (paresthesia) 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

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

Storage and Disposal of Metta SR

- Storage

- Store below 30°C. Protect from light and moisture.
- Keep out of reach of children.

- 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

METTA SR TABLETS 500 MG:

White to off-white coloured, capsule shaped, biconvex tablets with 'Torrent logo' debossed on one side and '500' on the other side.

METTA SR TABLETS 750 MG: Pale red colored, capsule shaped, biconvex tablets with 'Torrent logo' debossed on one side and '750' on the other side.

- Ingredients

Active ingredient

- Metformin Hydrochloride.

Inactive ingredients

- Lactose Monohydrate.
- Ammonio Methacrylate
- Copolymer Type B.
- Hydrogenated Castor Oil.
- Magnesium Stearate.
- Ferric Oxide Red (only for Metta SR 750mg).

- MAL number(s):

METTA SR TABLETS 500 MG:
MAL12020011AZ

METTA SR TABLETS 750 MG:
MAL12020016AZ

Manufacturer

Torrent Pharmaceuticals Limited
Indrad 382 721, Tal: Kadi,
City: Indrad, Dist. Mehsana,
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Product Registration Holder

METTA SR TABLET

Metformin Hydrochloride (500 mg, 750 mg)

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