

Metformin STELLA 850 mg Film-coated tablet

Active ingredient: Metformin hydrochloride 850 mg

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What Metformin STELLA 850 mg is used for

Metformin is used for the management of type 2 diabetes mellitus (also called Non-insulin-dependent), when dietary management and exercise alone does not result in adequate glycaemic (the presence of glucose in the blood) control. Metformin may be used as alone or in combination with other anti-diabetic agents or with insulin in adults.

Children from 10 years of age and adolescents can use metformin as alone or in combination with insulin.

In type 1 diabetes (also called insulin -dependent), metformin may be used as an adjuvant (pharmacological agent that modifies the effect of other drugs) to patients whose diabetic are poorly controlled.

How Metformin STELLA 850 mg works

Insulin is made naturally in the pancreas. It maintains the correct amount of sugar in the blood. People with type 2 diabetes are not able to make enough insulin or respond normally to the insulin their bodies make. When this happens, sugar (glucose) builds up in the blood, and this condition called diabetes mellitus.

Metformin helps control your blood sugar in a number of ways. These include helping your body respond better to the insulin it makes naturally, decreasing the liver glucose production and intestinal absorption of glucose, increasing the peripheral glucose uptake and utilization. As metformin does not cause your body to make more insulin, they rarely cause hypoglycemia (low blood sugar) when taken alone.

In type 1 diabetes, the combination of metformin HCl and insulin has been used in selected patients, but the clinical benefit of this combination has not been formally established.

Before you take Metformin STELLA 850 mg

When you must not take it

- If you have known allergy to metformin hydrochloride or any ingredient in the formulation.
- 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 severely reduced kidney function.
- If you have acute conditions with the potential to alter kidney function such as: dehydration (the loss of water and salts essential for normal body function), severe infection, shock (a medical emergency in which the organs and tissues of the body are not receiving an adequate flow of blood).
- If you have recently had an X-ray where iodinated contrast agents was injected.
- If you have acute or chronic disease which may cause tissue hypoxia (a lack in oxygen supply to tissue) such as: failure relating to heat or respiration, recent heart attack, shock (a medical emergency in which the organs and tissues of the body are not receiving an adequate flow of blood).
- If you have liver insufficiency, acute alcohol intoxication (the symptoms of poisoning due to alcohol), alcoholism (alcohol dependence).
- If you are nursing (breastfeeding) a child.

Before you start to take it

If any of the situations mentioned below apply to you, you should tell your doctor before taking this drug:

- If you are going to have a major surgery or an X-ray procedure with injection of dye. You may need to stop taking this drug for a certain of period of time.
- You should let your doctor know if you are pregnant or breast-feeding or wish to become pregnant or start breast-feeding.

Risk of lactic acidosis

- Metformin STELLA 850 mg 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 Metformin STELLA 850 mg 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, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.
- Stop taking Metformin STELLA 850 mg 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
 - + stomachache (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 Metformin STELLA 850 mg, 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

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

Tell your doctor if you are taking any of the following: other anti-diabetics (e.g. glyburide), diuretics (e.g. furosemide), nifedipine (treat high blood pressure and some heart conditions), cimetidine (treat reflux and ulcers).

How to take Metformin STELLA 850 mg

How much to take

Always take Metformin STELLA 850 mg as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Metformin STELLA 850 mg Film-coated tablet

Active ingredient: Metformin hydrochloride 850 mg

Adults:

- The usual starting dose is one tablet 2 or 3 times a day. Your doctor will tell you when to take this.
- After 10 to 15 days, your doctor may slowly increase your dose until the right dose for you is reached.
- The maximum daily dose is 3 g.

Children and adolescent:

Metformin STELLA 850 mg film-coated tablet can be used in children from 10 years of age and adolescents.

- The usual starting dose is one tablet 2 or 3 times a day. Your doctor will tell you when to take this.
- After 10 to 15 days, your doctor may slowly increase your dose until the right dose for you is reached.
- The maximum daily dose is 2 g.

When to take it

Metformin STELLA 850 mg is administered orally with or after meals. Try to take metformin at the same times each day to avoid missing any doses.

How long to take it

You should take this drug for as long as your doctor continues to prescribe it.

If you forget to take it

Take it as soon as you remember (with food) and continue taking it at the usual time. If it is nearly time for your next dose, leave out the missed dose; never take two doses at the time to compensate. If in doubt speak to your pharmacist or doctor.

If you take too much (overdose)

Contact your doctor or the nearest hospital for advice.

While you are using Metformin STELLA 850 mg

Things you must do

- The amount of sugar in your blood or urine should be checked regularly. Your doctor will also check your kidneys are working properly. This should be done at least once a year or more often if you are elderly or have kidney problems.
- The diet with regular distribution of carbohydrate intake during the day should be continued. The energy-restricted diet should be continued by overweight patients. The usual laboratory tests for diabetes monitoring should be performed regularly.

- If metabolic acidosis (a disruption of the body's acid-base balance) is suspected, metformin should be discontinued and the patients should be hospitalized immediately.

Things you must not do

Do not drink large amounts of alcohol or take medicines containing alcohol while taking metformin.

Things to be careful of

Metformin on its own does not usually affect your ability to drive. However, if you also take other medicines which lower blood sugar you may feel faint, dizzy, weak or shaky. If this happens, do not drive or use any tools or machines.

Side effects

Like all medicines, Metformin STELLA 850 mg can cause side effects, although not everybody gets them.

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

- Disorders relating to stomach and intestine include anorexia (an eating disorder), nausea, vomiting, and diarrhea or taste disturbance which lead to weight loss; Absorption of various substances including vitamin B₁₂ may be impaired.
- 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.

If any of the side effects get serious, or if you notice any other 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 npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Metformin STELLA 850 mg

Storage

The expiry date of this pack is printed on the box. Do not use this pack after this date.

Store in a well-closed container, in a dry place. Do not store above 30°C.

Keep out of reach of children.

Disposal

Medicines should not be disposed of via wastewater of 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

Metformin STELLA 850 mg appears as a white, oblong film-coated tablet with breaking notch on both sides.

Ingredients

Active ingredient: Metformin hydrochloride 850 mg.

The other ingredients: Hypromellose, povidone K25, magnesium stearate, opadry white 02F28644.

MAL Number: MAL13075062AZ

Manufacturer and Product Registration Holder

Manufacturer

STELLPHARM J.V. CO., LTD. - BRANCH 1

(A Joint Venture Company of Auxilto GmbH, Germany)

No. 40 Tu Do Avenue, Vietnam - Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam

Product Registration Holder

STADPHARM SDN. BHD.

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