

ROYCE METFORMIN FILM-COATED TABLET 500MG

Metformin Hydrochloride (500mg)

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What Royce Metformin Film-Coated Tablet 500mg is used for

Royce Metformin Film-Coated Tablet 500mg is indicated for a condition of diabetes mellitus when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose levels.

How Royce Metformin Film-Coated Tablet 500mg works

Metformin hydrochloride is an antihyperglycaemic with lowering plasma glucose concentrations after eating and fasting. It does not stimulate insulin secretion and therefore does not produce hypoglycaemia (low blood glucose).

Before you use Royce Metformin Film-Coated Tablet 500mg

-When you must not use it

Do not take Royce Metformin Film-Coated Tablet 500mg:

- 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-coma. Symptoms of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).

Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it:

Risk of lactic acidosis

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

Stop taking Royce Metformin Film-Coated 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 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 Royce Metformin Film-Coated 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.

-Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose of the other medications or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Royce Metformin Film-Coated Tablet 500mg:

- Alcohol and alcohol containing medicinal product.
- Iodinated contrast agents.
- Medicinal products with intrinsic hyperglycaemic activity (systemic and local routes, sympathetic nervous system).

How to use Royce Metformin Film-Coated Tablet 500mg

-How much to use:

Adults with normal renal function (GFR $\geq$ 90 mL/min):

Monotherapy and combination with other oral antidiabetic agents:

-The usual starting dose is one tablet 2 or 3 times daily given during or after meals. After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability.

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

-If transfer from another oral antidiabetic agent is intended: discontinue the other agent and initiate metformin at the dose indicated above.

Combination with insulin:

Metformin and insulin may be used in combination therapy to achieve better blood glucose control. Metformin hydrochloride is given at the usual starting dose of one tablet 2 or 3 times daily, while insulin dosage is adjusted on the basis of blood glucose measurements.

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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 and adolescents:

Monotherapy and combination with insulin

- Royce Metformin Film-Coated Tablet 500mg can be used in children from 10 years of age and adolescents.
- The usual starting dose is 500 mg metformin hydrochloride once daily, given during or after meals.

After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability. The maximum recommended dose of metformin hydrochloride is 2g daily, taken as 2 or 3 divided doses.

Renal impairment

A GFR should be assessed before initiation of treatment with metformin containing products and at least annually thereafter. In patients at an increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6 months.

GFR mL/min	Total maximum daily dose (to be divided into 2-3 daily doses)	Additional considerations
60-89	3000 mg	Dose reduction may be considered in relation to declining renal function.
45-59	2000 mg	Factors that may increase the risk of lactic acidosis should be reviewed before considering initiation of metformin. The starting dose is at most half of the maximum
30-44	1000 mg	

		dose.
<30	-	Metformin is contraindicated.

-When to use it:

Always take Royce Metformin Film-Coated Tablet 500mg exactly as your doctor has told you. You should check with your doctor if you are not sure.

-How long to use it:

Keep taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

-If you forget to use it:

Consult your doctor or pharmacist on what you should do if you forget to take a dose. Take the missed dose as soon as you remember. However, if it is almost time for your next dose, wait until the usual time to take your medicine. Do not double your dose to make up for the missed doses.

-If you use too much (overdose):

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately. You might need urgent medical attention. The signs and symptoms of overdose include:

- Lactic acidosis – medical condition when lactic acid accumulates in bloodstream).

While you are using Royce Metformin Film-Coated Tablet 500mg

-Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Royce Metformin Film-Coated Tablet 500mg.
- Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Royce Metformin Film-Coated Tablet 500mg to anyone

else, even if they have the same symptoms or condition as you.

-Things to be careful of

- Particular caution is recommended in patient with renal impairment.
- Caution is advised when it is used in combination with insulin or other antidiabetics.

Side effects

Like all medicines, Royce Metformin Film-Coated Tablet 500mg can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any of the side effects after taking this medicine:

- **Adverse reactions:** nausea, vomiting, diarrhea, abdominal pain and loss of appetite.
- **Metabolism and nutrition disorders:** lactic acidosis.
- **Nervous system disorders:** taste disturbance.
- **Gastrointestinal disorders:** nausea, vomiting, diarrhea, abdominal pain and loss of appetite.
- **Hepatobiliary disorders:** liver function abnormalities.
- **Skin and subcutaneous tissue disorders:** skin reactions (erythema, pruritus, urticaria).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-03-78835490, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and disposal of Royce Metformin Film-Coated Tablet 500mg

Storage:

Store in a dry place below 30°C. Protect from light.

Disposal:

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicine no longer required. These measures will help to protect the environment.

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Product description

-What it looks like:

White to off-white colour, round, shallow biconvex with single break line on one side and plain on the other side.

-Ingredients:

-Active Ingredients:

Metformin hydrochloride.

-Inactive Ingredients:

Magnesium stearate, opadry II white and purified water.

-MAL No.:

MAL

Mode of administration:

For oral use only.

Packaging Presentation:

Packed in aluminium/PVC blister of 10x10's, 50x10's & 100x10's.

Manufacturer and Product Registration Holder

Royce Pharma Manufacturing Sdn.
Bhd.

PT 1663, Nilai Industrial Estate,
71800 Nilai, Negeri Sembilan,
Malaysia.

Date of revision

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