

METCHEK 500/ METCHEK 850

Metformin Tablets BP (500mg, 850mg)

What is in this leaflet

1. What METCHEK is used for
2. How METCHEK works
3. Before you use METCHEK
4. How to use METCHEK
5. While you are using it
6. Side effects
7. Storage and Disposal of METCHEK
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What METCHEK is used for

METCHEK contains metformin hydrochloride that belongs to a group of active substances called biguanides, which are used to treat diabetes.

METCHEK is used in patients who have non-insulin-dependent (type 2) diabetes, particularly in overweight patients, where diet and exercise alone have failed to control it. Metformin can be given alone or in combination with other oral antidiabetic medicines or with insulin.

How METCHECK works

Insulin is a hormone produced by pancreas that makes your body take in glucose (sugar) from 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 properly use the insulin produced. This results in high glucose level in blood. METCHEK helps to lower blood glucose to as normal a level as possible.

Before you use METCHEK

- When you must not use it

Do not use METCHEK

- If you are allergic (hypersensitive) to metformin or any of the other ingredients of this medicine.
- If you have kidney or liver problems.
- If you have uncontrolled diabetes, with e.g., severe hyperglycemia (high blood glucose), nausea, vomiting, dehydration, rapid weight loss 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 include stomach pain, abnormal breathing and drowsiness (if severe)

- if you lost too much water from body (dehydration), such as due to long lasting or severe diarrhea, 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 (see "take special care with METCHEK").
- If you have a severe infection, which may lead to kidney problems and put you at risk for lactic acidosis (see "take special care with METCHEK").
- 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 (see "take special care with METCHEK")
- If you drink a lot of alcohol.
- If any of the above applies to you, talk to your doctor before start taking the medicine.

- Before you start to use it

Make sure you ask your doctor for advice, if

- You need to have examination such as X-ray or scan involving injection of contrast medicines that contain iodine into your bloodstream
- You need to have major surgery.

You must stop taking METCHEK for certain period of time before and after examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Take special care with METCHEK

Risk of Lactic acidosis

METCHEK 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 or reduced oxygen supply. Symptom of lactic acidosis are vomiting, stomach ache, muscle cramp, general feeling of not being well with severe tiredness and difficulty in breathing. Stop taking METCHEK and contact doctor or the nearest hospital immediately if you experience symptoms of lactic acidosis.

METCHEK on its own does not cause hypoglycemia (low blood glucose level). However, if you take METCHEK together with other medicines to treat diabetes that can cause hypoglycemia (such as sulphonylureas, insulin, meglitinides), there is risk of hypoglycemia. If you experience symptoms of hypoglycemia such as weakness, dizziness, increased sweating, fast heart beating, vision disorder or difficulty in concentration, it usually helps to eat or drink something containing sugar.

- Taking other medicines

If you need to have injection of contrast medicines that contain iodine into your bloodstream, for example X-ray or scan, you must stop taking METCHEK for a period of time before and after the examination. Tell your doctor if you take any of the following medicines and METCHEK at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of METCHEK.

- Diuretics (used to get rid of excess water)
- Beta-2 agonists (used to treat asthma)
- Glucocorticoids (used to treat inflammation)
- angiotensin-converting enzyme (ACE) inhibitors (used to treat high blood pressure)

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

METCHEK 500/ METCHEK 850

Metformin Tablets BP (500mg, 850mg)

How to use METCHEK

Always take METCHEK exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. METCHEK 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.

- How much to use

Children 10 years and over and adolescents

The usual starting dose is one tablet of 500mg or 850mg once daily, given during meals 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 dose of METCHEK is 2g daily, taken as 2 or 3 divided doses.

Adults

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 METCHEK is 3 g daily. If transfer from another oral anti-diabetic agent is intended: discontinue the other agent and initiate METCHEK at the dose indicated above.

Combination with insulin:

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

Elderly:

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

- When to use it

Two or three doses daily and taken during or after meals. Do not chew the tablets but swallow them whole with a glass of water.

- How long to use it

You should take your medicine for as long as your doctor tells you to. Do not stop taking the medicine without talking to your doctor first.

- If you forget to use it

If you forget to take a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Never double the next dose to make up for the one missed.

- If you use too much (overdose)

If you have taken more METCHEK than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are vomiting, 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. Contact a doctor or the nearest hospital straight away.

While you are using METCHEK

- Things you must do

Pregnancy and breastfeeding:

You must tell your doctor if you think you are (or might become) pregnant. During pregnancy, diabetes should be treated with insulin. If you find out that you are pregnant while taking METCHEK consults your doctor so that they may change your taking. Do not take METCHEK if you are breast-feeding or if you are planning to breast-feed your baby. Ask your doctor or pharmacist for advice before taking any medicine.

- Things you must not do

Taking METCHEK with food and drink:

- Do not drink alcohol when you take this medicine. Alcohol may increase risk of lactic acidosis especially if you have liver problems or undernourished. This also applies to medicine 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 METCHEK, or change dose, without checking with your doctor.

- Things to be careful of

Driving and using machines

METCHEK does not affect your ability to drive or use machine. However, there is an increased risk of low blood sugar levels if METCHEK is taken with other medicines for diabetes (sulphonylureas, insulin or repaglinide). This may cause dizziness and fainting. Do not drive or operate machines if you are affected.

Side effects

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

If you experience the following, tell your doctor immediately or go to the emergency department of your nearest hospital:

If you have symptoms which included muscle cramps, stomach pain, breathless and feeling of being very weak and unwell; this could indicate you have lactic acidosis, a serious but very rare side effect of metformin.

The side effects of medicines are classified as follows:

Very common: happening in more than 1 person in 10

- Nausea (feeling sick)
- Vomiting
- Diarrhoea
- Abdominal pain (stomach pain)
- Loss of appetite

Common: happening less than 1 person in 10 but more than 1 person in 100

- Taste disturbances
- Decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles

METCHEK 500/ METCHEK 850

Metformin Tablets BP (500mg, 850mg)

(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 gets serious, or if you notice any 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 METCHEK

- Storage

Keep out of the reach and sight of children. If a child is treated with METCHEK, parents and caretakers are advised to oversee how this medicine is used. Do not use METCHEK after the expiry date which is stated on the carton or the blister after "EXP".

Store below 30°C and protect from light.

- 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

METCHEK 850 MG (Metformin tablet 850 mg)

White to off white, circular, beveled edged, biconvex, film coated tablets.

METCHEK 500 MG (Metformin tablet 500 mg)

White to off white, circular, beveled edged, biconvex, film coated tablets.

- Ingredients

- Active ingredient (s)

Metformin Hydrochloride

- Inactive ingredients

Povidone (PVP K -30) BP, Maize starch BP, Magnesium stearate BP, Colloidal anhydrous silica BP, Hypromellose E – 15 USP, Macrogols 6000 BP, Purified talc BP, Titanium dioxide BP, Propylene glycol BP and purified water

- MAL number:

METCHEK 850 MG (Metformin tablet 850 mg):

MAL08031360A

METCHEK 500 MG (Metformin tablet 500 mg):

MAL08031359A

Manufacturer

Indoco Remedies Limited
L-14, Verna Industrial Area, Verna,
Goa 403722. India.

Product Registration Holder

Unimed Sdn Bhd
No 53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200 Kuala Lumpur.

Date of revision

22/07/2024

Serial Number

NPRA(R2/1)2312014/1184