METCHEK TABLET 500 MG/850 MG

(Metformin BP 500 mg/850 mg)

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What METCHEK is used for

1. METCHEK contains the active substance metformin hydrochloride that belongs to a group of active substances called biguanides, which are used to treat diabetes by regulating the level of sugar in the blood.
2. 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 METCHEK works

METCHEK is an anti-hyperglycemic agent, which improves glucose tolerance in type 2 diabetes subjects, lowering both plasma glucose of postprandial and basal. METCHEK decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity (increases peripheral glucose uptake and utilization). With METCHEK therapy, insulin secretion remains unchanged while fasting insulin levels and daylong plasma insulin response may actually decrease. In short, this medicine works by reducing the level of sugar in the blood.

Before you use METCHEK

- When you must not use it

Hypersensitivity to METCHEK or to any of the other excipients of METCHEK.

Diabetic ketoacidosis, diabetic pre-coma

Renal failure or renal dysfunction (creatinine clearance < 30mL/min)

Acute condition with the potential to alter renal function such as:

- Dehydration
- Severe infection
- Shock

Acute or chronic disease, which may cause tissue hypoxia such as:

- Cardiac or respiratory failure
- Recent myocardial infection
- Shock
- Hepatic insufficiency, acute alcohol intoxication, alchololism
- Lactation

- Before you start to use it

As METCHEK is excreted by the kidney, serum creatinine levels should be determined before initiating treatment and regularly thereafter: at least annually in patients with normal renal function, at least two to four times a year in patients with serum creatinine levels at the upper limit of normal and in elderly subjects.

The diagnosis of type 2 diabetes mellitus should be confirmed before treatment with is initiated. No effect of METCHEK on growth and puberty has been detected during controlled clinical studies of one-year duration but no long-term data on these specific points are available. Therefore, a careful follow-up of the effect of METCHEK on these parameters in METCHEK-treated children, especially pre-pubescent children, is recommended.

Pregnancy and breast feeding
Pregnancy
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.
Breast Feeding
Do not takes METCHEK if you are breast-feeding or if you are palnning to breast-feed your baby.
Ask your doctor or pharmacist for advice before taking any medicine.
Use in children and adolescents
METCHEK can be used in children from 10 years of age and adolescents. The usual starting dose is one tablet of 500 mg or 850 mg 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 recommended

dose of METCHEK is 2 g daily, taken as 2 or 3 divided doses.

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.

- 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.

Certain medicines are especially likely to affect the amount of sugar in your blood:

- glucocorticoids (used to treat inflammation)
- beta-2-agonists (used to treat asthma)
- diuretics (used to get rid of excess water)
- angiotensin-converting enzyme (ACE) inhibitors (used to treat high blood pressure)

Tell your doctor or pharmacist if you are taking any of these. Your blood sugar will be checked, and your dose of Competact may need to be changed.

Concomitant use not recommended:

Alcohol increases risk of lactic acidosis in acute alcohol intoxication, particularly in case of:

- Fasting or malnutrition
- Hepatic insufficiency

Avoid consumption of alcohol and alcohol-containing medications

How to use METCHEK

- How much to use

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)

Hypoglycaemia has not been seen with METCHEK doses of up to 85g, although lactic acidosis has occurred in such circumstances. High overdose or concomitant risks of METCHEK may lead to lactic acidosis. Lactic acidosis is a medical emergency and must be treated in hospital. The most effective method to remove lactate and METCHEK is haemodialysis.

While you are using it

- Things you must do

The tablets should be swallowed with a glass of water. You should try to take your daily dose at about the same time each day.

- Things you must not do

None.

- Things to be careful of

None.

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 casualty department of your nearest hospital:

If you have symptoms which included muscle cramps, stomach pain, breathless and felling 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

Very rare: happening in less than 1 person in 10,000s

- Decrease in vitamin B12: Over this time may lead to anemia, a sore mouth or tongue, or possibly numbness or tingling in the limbs.
- Redness and itching of the skin, hives (nettle rash)

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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of METCHEK

- Storage

Do not store above 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waster. 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
B-20, M.I.D.C.
Waluj, Aurangabad 431 136 India.

Product Registration Holder
Unimed Sdn Bhd
No 53, Jalan Tembaga SD 5/2B,
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52200 Kuala Lumpur.

Date of revision

- 06/07/2013