

BROT TABLET

Metformin hydrochloride 500mg, 850mg

What is in this leaflet

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

What BROT is used for

- Treatment of type 2 mellitus in adults, particularly in overweight individuals, when dietary management and exercise alone does not result in adequate glycaemic control.
- BROT may be used as monotherapy or in combination with other antidiabetic agents, or with insulin.

How BROT works

- BROT contains the active substance metformin hydrochloride which is a member of a class of medicines called biguanide that lowers blood sugar levels in individual with type 2 diabetes mellitus.

Before you use BROT

When you must not use it

Do not take BROT:

- If you are allergic (hypersensitive) to metformin or any other ingredients of this medicine.
- 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 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).

Before you start to use it

Talk to your doctor or pharmacist before taking BROT if you have or have had:

- allergic reaction to metformin or any of the ingredients in the tablet. (An allergic reaction may include a rash, itching or difficulty breathing)
- diabetic ketoacidosis, diabetic pre-coma
- liver problems or you have severely reduced kidney function

- treated for acute heart failure or have recently had a heart attack

Risk of lactic acidosis

BROT 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 condition in which a part of the body has 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 BROT 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 BROT 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 BROT, 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.

Pregnancy and breast-feeding

- Tell your doctor if you are, you think you might be or are planning to become pregnant, so that he or she may change your treatment.
- Metformin is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking:

- Medicines which increase urine production (diuretics)
- Beta-2 agonists such as salbutamol or terbutaline (used to treat asthma)
- Medicines used to treat pain and inflammation (NSAIDs and COX-2 inhibitors)
- Other medicine used to treat diabetes
- Certain medicines for treatment of high blood pressure (ACE inhibitors)
- Alcohol-containing medications.

It is important that you tell your doctor, nurse or pharmacist about all the medicines that you are taking including those bought without a prescription.

How to use BROT

How much to use

The adult starting dose is one tablet 2 or 3 times daily given during or after meals. If for children over 10 years old, the starting dose is one tablet once daily with food or after food. The dose shall be adjusted on the basis of blood glucose measurements after 10 or 15 days.

If you are an elderly, your doctor may adjust the dosage based on renal function. Regular assessment of renal function is necessary.

When to use it

- Always take this medicine exactly as your doctor has told you.
- You can take this medicine with or after food.
- Do not crush or chew the tablets. Swallow each tablet with a glass of water.

How long to use it

- Continue to take this medicine as long as your doctor prescribes to help control your blood sugar. You should not stop taking this medicine without talking to your doctor first.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to use it

- If you forget to take a tablet, take one as soon as you remember. Do not take a double dose (two doses at the same

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time) to make up for a forgotten dose. Take the next dose at the usual time.

If you use too much (overdose)

- If you have taken more than you should have, you may experience lactic acidosis. Stop taking BROT immediately and contact a doctor or go to the nearest hospital straight away.

While you are using it

Things you must do

- BROT 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.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Things you must not do

- Children under 10 years old should not use BROT.
- Concomitant use of alcohol is not recommended.
- This medicine has been prescribed for you only. Do not pass it on to others, even if their signs of illness are the same as yours.

Things to be careful of

- If you experience some of the symptoms of lactic acidosis, stop taking BROT and contact a doctor or go to the nearest hospital immediately.

Driving and using machines

- BROT will not affect your ability to drive or use machines.
- Take special care if you take BROT together with other medicines to treat diabetes that can cause hypoglycaemia. Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects are as below:

- Feeling sick (nausea), diarrhoea, abdominal pain, loss appetite
- Metallic taste
- Skin reactions such as redness of the skin, itching or an itchy rash

- Rarely, lactic acidosis

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 (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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of BROT

Storage

- Keep this medicine out of sight and reach of children.
- Store below 30°C in the original package.

Disposal

- Do not use this medicine after the expiry date stated on the carton and tablet blister.
- Do not throw away any medicines via wastewater or household waste. Ask you pharmacist how to throw away medicines you no longer required. These measures will help protect the environment.

Product description

What it looks like

- BROT 500mg: White, oval film-coated tablet, plain on both sides with dimension of nucleus 16mm x 8mm
- BROT 850mg: Yellow, oval, film-coated tablet, embossed MC on one side and plain on the other, with dimension of nucleus 20.1mm x 9.8mm

Ingredients

Active ingredient

The active substance is metformin hydrochloride.

Inactive ingredients

The other ingredients are:

- Croscarmellose sodium, Povidone K30, Microcrystalline cellulose, Magnesium stearate, Opadry II White

85F18422, Yellow iron oxide (Brot 850mg Tablet only)

MAL number:

- BROT 500mg Tablet
MAL19870413AZ
- BROT 850mg Tablet
MAL09011420AZ

Manufacturer

Medochemie (Far East) Ltd. (Oral Facility), No. 40, VSIP II Street 6, Vietnam-Singapore Industrial Park II, Binh Duong Industry-Service-Urban Complex, Hoa Phu ward, Thu Dau Mot city, Binh Duong province, Vietnam

Product registration holder

Komedic Sdn Bhd, 4 Jalan PJS 11/14, Bandar Sunway, 46150 Petaling Jaya, Selangor D.E.

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