



BROT 500mg and 850mg tablets **Metformin hydrochloride**

PACKAGE LEAFLET: INFORMATION FOR THE USER

PLEASE READ THIS LEAFLET CAREFULLY. IT CONTAINS IMPORTANT INFORMATION ABOUT YOUR MEDICINE

1. DESCRIPTION

The name of the tablets you have is BROT. They contain either 500mg or 850mg of metformin hydrochloride as the active ingredient.

"BROT" 500mg tablets are white, round shaped and they also contain crosscarmellose sodium, powdered cellulose, povidone, cellulose microcrystalline, calcium stearate, polyvinyl alcohol, titanium dioxide (E171), talc, lecithin, xanthan gum and macrogol 6000 as inactive ingredients.

"BROT" 850mg tablets are white, oval shaped and they also contain macrogol 4000, powdered cellulose, povidone, calcium stearate, polyvinyl alcohol, titanium dioxide (E171), talc, lecithin, xanthan gum and macrogol 6000 as inactive ingredients.

Boxes of 30, 50, 100 tablets and hospital pack are available.

The licence holder and manufacturer of "BROT" is Medochemie Ltd, 1-10 Constantinoupoleos street, 3011, Limassol, Cyprus.

2. WHAT YOU SHOULD KNOW ABOUT THE MEDICINE YOUR DOCTOR PRESCRIBED

Therapeutic indications

"BROT" (metformin HCl) is used for the management of diabetes (high blood sugar). You may take it alone or in combination with other drugs used for the same reason. It is always used in combination with a diet that restricts sugars and fats. You may also take "BROT" together with your insulin treatment.

Contra-indications

- Do not take "BROT" if you previously had any allergic reaction to its components.
- Do not take "BROT" if you are under 12 years old.
- Tell your doctor if you are pregnant or trying to become pregnant. You may have to change your treatment so as to manage your diabetes. If you are breast feeding you should not take "BROT".

You should not take "BROT" if you have any of the following conditions:

- Liver disorder
- Kidney disorder
- Problems with your heart (such as a recent myocardial infarction or heart failure)
- Problems with your lungs
- If you are consuming large quantities of alcohol.

If you are not sure whether you have any of these conditions consult your doctor.

Precautions

If you intend to have an operation or any other procedure where a contrast fluid needs to be administered intravenously, notify your doctor that you are taking metformin. In most cases it is necessary to stop taking your medicine 2 to 3 days before the operation. Your doctor will tell you when to start your treatment again. If you suffer from any severe infection tell it to your doctor. You may have to stop taking "BROT". Most of the drugs used for the management of diabetes may cause hypoglycaemia (low blood sugar). This may cause faintness, sweating, tremor, weakness and confusion. It is not usual to experience hypoglycaemia when you are taking "BROT" alone; but it is possible to have this reaction if you are taking other drugs at the same time.

If you are taking insulin you have to be very careful, especially at the beginning of treatment. During your treatment with "BROT" it may be necessary to do some blood tests so as to check your kidney function and some other parameters. Your doctor will tell you which tests you have to do and how often.

Drug Interactions

If you are taking any other drugs, even those you buy without medical prescription, tell your doctor what they are. You should be cautious if you take BROT, sulphonylurea (drugs used for the management of diabetes), cimetidine (for stomach ulcer or other similar conditions) or anticoagulant agents (prevent blood clots).

Dosage and Administration

Your doctor will decide how much BROT you need to take. The dosage regime described below are indicative.

The usual starting dose is one 850 mg tablet two times daily or one 500 mg tablet three times daily, during or at the end of a meal. The desired effect can be achieved within a few days or can be delayed up to two weeks. After that period your doctor will decide if you have to take more tablets.

Overdosage

In case you took too many tablets of BROT concurrently with sulphonylurea insulin or alcohol you will become hypoglycaemic. You should immediately call a doctor or hospital to get immediate treatment. Always remember to take the both of your medicine with you to show it to the medical staff.

Signs of hypoglycemia (low blood sugar) such as hunger, headache, confusion, irritability, drowsiness, weakness, dizziness, tremors, sweating, fast heartbeat, seizure (convulsions), fainting, or coma.

An overdose of BROT may cause a life-threatening condition called lactic acidosis. Get emergency medical help if you have any of these symptoms of lactic acidosis: weakness, increasing sleepiness, slow heart rate, cold feeling, muscle pain, shortness of breath, stomach pain, feeling light-headed and fainting.

What you should do in case you missed a dose

If you forget to take a tablet, take it as soon as possible. Be sure to take the medicines with food. If it is nearly time to take your next dose omit the dose you forgot completely. Then go on as before. Do not duplicate the dose.

Adverse reactions

Metformin may sometimes cause gastro-intestinal disturbances, which could be avoided by taking the drug with or immediately after food. These symptoms may appear at the beginning of the treatment and then disappear spontaneously.

Any adverse reaction you notice and you think is due to your medication should be reported to your doctor or pharmacist to enable prompt treatment.

Expiration date of the product

The expiration date is printed on both the outer and inner package of this product. Do not use the product after that date.

Storage precautions

Store BROT tablets at room temperature (up to 25°C) in a dry place.

3. INFORMATION ABOUT THE CORRECT USE OF MEDICINES

- This drug is only for you. You should take it only for the disease it was prescribed for.
- If you have questions about the way you should take this drug, or if you have any problems that you think are related to the drug, contact your doctor or pharmacist. He will give you more information.
- In order to be safe and efficacious any drug should be taken according to your doctor's instructions. You should also carefully read the information leaflet.
- Do not keep medicines in places with high temperature or humidity (like the bathroom). Also do not expose them to direct sunlight.
- If the appearance of this medicine is changed or if the product has expired do not use it.
- Keep all medicines out of the reach of children.

4. BROT tablets are administered with medical prescription only.

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Medochemie Ltd., Limassol Cyprus

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