**Package leaflet: Information for the patient**

**Brotmin 500 mg film-coated tablets**
**Brotmin 850 mg film-coated tablets**
**Brotmin 1000 mg film-coated tablets**
metformin hydrochloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Brotmin is and what it is used for
2. What you need to know before you take Brotmin
3. How to take Brotmin
4. Possible side effects
5. How to store Brotmin
6. Contents of the pack and other information


## 1. What Brotmin is and what it is used for

Brotmin contains metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides.

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

If you are an overweight adult, taking metformin over a long period of time also helps to lower the risk of complications associated with diabetes. Metformin is associated with either a stable body weight or modest weight loss.

Brotmin is used to treat patients with type 2 diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients.

Adults can take Brotmin on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).

Children 10 years and over and adolescents can take Brotmin on its own or together with insulin.

## 2. What you need to know before you take Brotmin

**Do not take Brotmin**
- If you are allergic to metformin hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have liver problems

- If you have severely reduced kidney function
- If you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (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 include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- If you lost too much water from your body (dehydration), such as due to long-lasting or severe diarrhoea, 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 'Warnings and precautions').
- If you have a severe infection, such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- If you are treated for acute 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 'Warnings and precautions').
- If you drink a lot of alcohol.

If any of the above applies to you, talk to your doctor, before you start taking this medicine.

Make sure you ask your doctor for advice, if:
- You need to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your bloodstream.
- You need to have major surgery.

You must stop taking metformin for a certain period of time before and after the 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.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Brotmin.

**Risk of lactic acidosis**
Metformin 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 (see further information below), 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.

*Talk to your doctor promptly for further instructions if:*
- You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
- You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

**Stop taking Brotmin 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 Brotmin 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
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

If you need to have major surgery you must stop taking Brotmin during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Brotmin.

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

During treatment with metformin, 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.

**Other medicines and Brotmin**

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Brotmin before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Brotmin.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of Brotmin. It is especially important to mention the following:

- Medicines which increase urine production (diuretics).
- Medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- Beta-2 agonists such as salbutamol or terbutaline (used to treat asthma).
- Corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma).
- Medicines that may change the amount of metformin in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprime, vandetanib, isavuconazole, crizotinib, olaparib).
- Other medicines used to treat diabetes.

**Brotmin with food, drink and alcohol**

Avoid excessive alcohol intake while taking metformin since this may increase the risk of lactic acidosis (see section 'Warnings and precautions').

**Pregnancy, breast-feeding and fertility**

If you are pregnant, think you may be pregnant or are planning to have a baby, speak to your doctor in case any changes will be needed to your treatment or monitoring of your blood glucose levels.
This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

**Driving and using machines**

Metformin on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines.

However, take special care if you take metformin together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides). 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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 3. How to take Brotmin

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

Brotmin 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.

The recommended dose is
**Adults** usually start with 500 mg or 850 mg Brotmin two or three times a day. The maximum daily dose is 3000 mg taken as 3 divided doses.
If you have reduced kidney function, your doctor may prescribe a lower dose.
**If you take insulin too**, your doctor will tell you how to start Brotmin.

**Use in children and adolescents**
Children 10 years and over and adolescents usually start with 500 mg or 850 mg Brotmin once a day. The maximum daily dose is 2000 mg taken as 2 or 3 divided doses. Treatment of children between 10 and 12 years of age is only recommended on specific advice from your doctor, as experience in this age group is limited.

**Monitoring**
- Your doctor will perform regular blood glucose tests and will adapt your dose of Brotmin to your blood glucose levels. Make sure that you talk to your doctor regularly. This is particularly important for children and adolescents or if you are an older person.
- Your doctor will also check at least once a year how well your kidneys work. You may need more frequent checks if you are an older person or if your kidneys are not working normally.

**How to take Brotmin**
Take Brotmin with or after a meal. This will avoid you having side effects affecting your digestion.
Do not crush or chew the tablets. Swallow each tablet with a glass of water.
- If you take one dose a day, take it in the morning (breakfast).
- If you take two divided doses a day, take them in the morning (breakfast) and evening (dinner).
- If you take three divided doses a day, take them in the morning (breakfast), at noon (lunch) and in the evening (dinner).

If, after some time, you think that the effect of Brotmin is too strong or too weak, talk to your doctor or pharmacist.

**If you take more Brotmin than you should**
If you have taken more metformin that you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are non-specific such as vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat. **If you experience some of these symptoms, you should seek immediately medical attention, as lactic acidosis may lead to coma. Stop taking Brotmin immediately and contact a doctor or the nearest hospital straight away.**

**If you forget to take Brotmin**
Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects may occur:
Metformin may cause a very rare (may affect up to 1 in 10,000 people), but very serious side effect called lactic acidosis (see section 'Warnings and precautions'). If this happens you must **stop taking Brotmin and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

**Very common side effects** (may affect more than 1 in 10 people)
- Digestive problems, such as feeling sick (nausea), being sick (vomiting), diarrhoea, bellyache (abdominal pain) and loss of appetite. These side effects most often happen at the beginning of the treatment with metformin. It helps if you spread the doses over the day and if you take Brotmin with or straight after a meal. If symptoms continue, stop taking Brotmin and talk to your doctor.

**Common side effects** (may affect up to 1 in 10 people)
- Changes in taste.
- 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.

**Very rare side effects** (may affect up to 1 in 10,000 people)
- Lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly. Symptoms of lactic acidosis are non-specific (see section 'Warning and precautions')
- Abnormalities in liver function tests or hepatitis (inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes). If this happens to you, stop taking Brotmin and talk to your doctor.
- Skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).

**Additional side effects in children and adolescents**
Limited data in children and adolescents showed that adverse events were similar in nature and severity to those reported in adults.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
**Malta**
the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.

**Cyprus**
Pharmaceutical Services
Ministry of Health
CY-1475 Nicosia
Tel: +357 22608607
Fax: + 357 22608669
Website: www.moh.gov.cy/phs

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Brotmin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Brotmin contains**
- The active substance is metformin hydrochloride.

Each film-coated tablet contains 500 mg metformin hydrochloride corresponding to 390 mg metformin base.
Each film-coated tablet contains 850 mg metformin hydrochloride corresponding to 662.9 mg metformin base.
Each film-coated tablet contains 1000 mg metformin hydrochloride corresponding to 780 mg metformin base.

- The other ingredients are Cellulose, Microcrystalline, Croscarmellose sodium, Povidone K30, Magnesium stearate.
  Film coat:
  *500 mg and 1000 mg*: Poly(vinyl alcohol), Titanium dioxide (E171), Macrogols, Talc
  *850 mg*: Iron oxide yellow (E172), Poly(vinyl alcohol), Titanium dioxide (E171), Macrogols, Talc

**What Brotmin looks like and contents of the pack**
Brotmin 500 mg film coated tablets: White oval film-coated tablets, plain on both sides, with dimensions 16mm x 8mm
Brotmin 850 mg film coated tablets: Yellow oval film-coated tablets, embossed 'MC' on one side and plain on the other side, with dimensions 20.1mm x 9.8mm
Brotmin 1000 mg film coated tablets: White oval film-coated tablets, with a score line on both sides, with dimensions 21.2mm x10.2mm. The tablet can be divided into equal doses.

*500 mg tablets:*
The tablets are supplied in blister packs of 9, 20, 21, 30, 40, 50, 56, 60, 84, 90, 100, 120, 200, 500, 600 or 1000 tablets.

Not all pack sizes may be marketed.

*850 mg and 1000 mg tablets:*
The tablets are supplied in blister packs of 8, 9, 10, 14, 20, 21, 30, 40, 50, 56, 60, 84, 90, 100, 120, 300, 600 or 1000 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**
Medochemie Ltd.,
1-10 Konstantinoupoleos street, 3011 Limassol, Cyprus

**Manufacturer**
Medochemie Ltd (Factory AZ)
2 Michali Irakleous Street,
Agios Athanassios, Industrial Area,
4101, Agios Athanassios, Limassol,
Cyprus

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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