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Package leaflet: Information for the user

Bramox® 2.5 mg tablets
Bramox® 5 mg tablets
Bramox® 10 mg tablets

Midodrine Hydrochloride

Brancaster PHARMA

BR-UK-P-Z-008

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 Bramox tablets are and what they are used for

The name of your medicine is Bramox tablets. They contain the medicine midodrine hydrochloride. This belongs to a group of medicines called adrenergic and dopaminergic agents. Midodrine hydrochloride is a medicine that raises your blood pressure and is used to treat certain severe forms of low blood pressure in adults when other treatments have not worked.

2 What you need to know before you take Bramox tablets

DO NOT TAKE BRAMOX TABLETS IF:

- you are allergic to midodrine hydrochloride or any of the other ingredients of this medicine (listed in section 6 of this leaflet)
- you have high blood pressure
- you have a slow pulse
- you have difficulty urinating
- you have certain forms of cardiovascular disease
- you have elevated pressure in the eye (glaucoma) or poor vision as a result of diabetes
- you have an overactive thyroid gland
- you have hormonal disorders caused by a tumour in the adrenal medulla (pheochromocytoma)
- you have severe kidney disease
- you have an enlarged prostate

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you have been told you have high blood pressure when you lie down. If this applies to you then:

Regular monitoring of your blood pressure when you are lying down and when you are standing up will be required as there may be a risk of your blood pressure rising when you lie down, for example, at night. If your blood pressure does go up when you lie down and reducing the dose does not correct this problem, then treatment with this medicine must be stopped.

It is important that you do not take this medicine late in the evening. Take your last daily dose at least 4 hours before you go to bed. By keeping your head elevated at night the potential risk of your blood pressure rising when you lie down is reduced.

Also talk to your doctor if you:

- have a serious disorder of the nervous system (autonomic nevous system disorders), since taking this medicine may lead to a further drop in blood pressure when you stand up. If this occurs, further treatment with this medicine should be stopped.
- suffer from problems with your blood circulation, especially if you have symptoms such as pain or cramps in the stomach after eating, or pain or cramps in the legs while walking.
- suffer from a disease of the prostate, as you may find passing urine is difficult when taking this medicine.

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You should have your kidney function and blood pressure checked by your doctor before you start using this medicine. During treatment with this medicine, your blood pressure will be checked from time to time, and if necessary your dose adjusted.

It is important that you immediately report symptoms related to high blood pressure, such as chest pain, palpitations, shortness of breath, headache and blurred vision. Your doctor will then decide whether to adjust dosage or discontinue your treatment with Bramox tablets.

If any of the warnings apply to you, or have in the past, talk to your doctor.

Children and adolescents
Do not give this medicine to children and adolescents under the age 18 because the safety and efficacy of Bramox tablets in this age group have not been established.

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

IN PARTICULAR, TELL YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING ANY OF THE FOLLOWING:

- Concomitant use with these medicines may cause a large increase in blood pressure:
  - Reserpine and guanethidine (medicines used to reduce high blood pressure)
  - Antihistamines (used to treat allergies)
  - Hormones for the thyroid (used when the thyroid is not working properly)
  - Tricyclic antidepressants and MAO-inhibitors (both used to treat depression)
  - Other vasoconstrictors (medicines that narrow blood vessels), or sympathomimetic agents (medicines that have a stimulating effect on certain parts of the nervous system).
- Prazosin and phentolamine (medicines used to treat heart disease) because the effect of this medicine is blocked by these drugs.
- Digitalis preparations (medicines used to treat heart disease) because concomitant use with this medicine may lead to cardiac dysfunction.
- Corticosteroids, such as fludrocortisone acetate (an anti-inflammatory medicine), because these medicines may increase its effect.
- Medicines which directly or indirectly reduce your heart rate because if this medicine is combined with these medicines, it is advisable that your doctor closely monitors you.

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Pregnancy and breast-feeding
Using this medicine while pregnant is not recommended, or if you are a woman of childbearing potential not using contraception. Tell your doctor if you are pregnant, or want to be, while you are being treated with this medicine.

Do not use this medicine while breast-feeding.

Driving and using machines
This medicine should not affect your ability to drive or use machines. However, you must be careful if dizziness or light-headedness occurs after taking this medicine.

Bramox 5 mg tablets contain Sunset Yellow FCF aluminium lake (E110)
Sunset Yellow FCF aluminium lake (E110) can cause allergic reactions.

3 How to take Bramox tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Swallow tablets with a drink of water. This medicine may be taken with or without food.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

How much you should take
Your doctor will decide your dose and tell you how long you should take this medicine. The treatment is usually long-term.

The recommended starting dose is normally one tablet of 2.5 mg three times a day. This dose can be increased weekly up to 10 mg three times daily, which is the usual maintenance dose of 30 mg per day. The recommended total daily dose should be spread evenly into three doses per day.

Timing of the evening dose
Avoid taking this medicine in the late evening. The last dose should be taken at least 4 hours before your bedtime. Elevating your head at night reduces the potential risk of high blood pressure when you lie down. More information can be found in the section “Warnings and precautions” of this leaflet.

If you feel that the effect of this medicine is too strong, or too weak, talk to your doctor or pharmacist.

If you take more Bramox tablets than you should
If you have used too much of this medicine please contact your doctor or pharmacist immediately.

Taking too much of this medicine can cause:
High blood pressure (hypertension), e.g. palpitations, shortness of breath, chest pain, headache and blurred vision; slow heart rate (bradycardia); difficulty urinating; goosebumps; feelings of coldness.

If you forget to take Bramox tablets
If you forget to take a dose, take your next dose as usual and then keep taking your medicine as your doctor has told you. Do not take a double dose to make up for a forgotten dose, because this will increase the risk of high blood pressure when you lie down.

If you stop taking Bramox tablets
There will be no sudden drop in your blood pressure. Always talk to your doctor if you are considering stopping taking this medicine. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

LIKE ALL MEDICINES, BRAMOX TABLETS CAN CAUSE SIDE EFFECTS, ALTHOUGH NOT EVERYBODY GETS THEM.

Very common (may affect more than 1 in 10 people): goosebumps, itching of the scalp and pain when urinating.

Common (may affect more than 1 in 100 but less than 1 in 10 people): tingling and itching, increased blood pressure when lying down, headache, nausea (feeling sick), heartburn, inflammation of the lining inside the mouth, flushing, rash, chills, difficulty urinating.

Uncommon (may affect more than 1 in 1,000 but less than 1 in 100 people): sleep disturbances including difficulty sleeping, restlessness, agitation and irritability, slowed heart rate, urge to urinate.

Rare (may affect more than 1 in 10,000 but less than 1 in 1,000 people): palpitations, rapid heartbeat, abnormal liver function including an increase in the number of liver enzymes.

Not known (frequency cannot be estimated from the available data): abdominal pain, being sick (vomiting), diarrhoea, anxiety, feelings of confusion.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Bramox tablets

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 outer carton and blister foil. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

6 Contents of the pack and other information

WHAT BRAMOX TABLETS CONTAIN:

The active substance is midodrine hydrochloride.
Each tablet contains 2.5 mg, 5 mg or 10 mg midodrine hydrochloride.

The other ingredients are microcrystalline cellulose, maize starch, magnesium stearate, and silica colloidal anhydrous.

Bramox 5 mg tablets also contain Sunset Yellow FCF aluminium lake (E110).

Bramox 10 mg tablets also contain Brilliant Blue FCF aluminium lake (E133).

What Bramox tablets look like and contents of the pack
The 2.5 mg tablets are white, round tablets marked on one side with “MID” above the score line and “2.5” below the score line.

The 5 mg tablets are orange, round tablets marked on one side with “MID” above the score line and “5” below the score line.

The 10 mg tablets are blue, round tablets marked “APO” on one side, with “MID” above the score line and “10” below the score line on the other side.

This medicine is available in cartons of 50 or 100 tablets in aluminium/aluminium blister packs. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Brancaster Pharma Limited, Church House, 48 Church Street, Reigate, Surrey RH2 0SN, United Kingdom.

Manufacturer

CampusPharma AB
Karl Gustavsgatan 1 A
Gothenburg, 411 25, Sweden.

Cross Vetpharm Group UK Limited, Unit 2, Bryn Cefni, Llangefni, Anglesey LL77 7XA, United Kingdom.

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands: Midodrine HCl Brancaster 2,5 mg tabletten, Midodrine HCl Brancaster 5 mg tabletten and Midodrine HCl Brancaster 10 mg tabletten.

UK: Bramox 2.5 mg tablets, Bramox 5 mg tablets and Bramox 10 mg tablets.

Denmark, Norway, Sweden: Hypotron 2,5 mg tabletter, Hypotron 5 mg tabletter and Hypotron 10 mg tabletter.

Finland: Hypotron 2,5 mg tabletit, Hypotron 5 mg tabletit and Hypotron 10 mg tabletit.

Iceland: Hypotron 2,5 mg töflur, Hypotron 5 mg töflur and Hypotron 10 mg töflur.

Detailed information on this medicine is available on the Medicines and Healthcare Products Regulatory Agency (MHRA) website: **http://www.mhra.gov.uk**

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Brancaster PHARMA

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