

## **Package leaflet: Information for the patient**

### **Bromocriptine 2.5 mg tablets** bromocriptine mesilate

**Read all of this leaflet carefully before you start using 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 symptoms 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 Bromocriptine is and what it is used for
2. What you need to know before you take Bromocriptine
3. How to take Bromocriptine
4. Possible side effects
5. How to store Bromocriptine
6. Contents of the pack and other information

#### **1. What Bromocriptine is and what is it used for**

Bromocriptine belongs to a group of medicines called dopamine agonists and prolactin inhibitors.

It works by increasing the release of dopamine in the brain, which treats diseases where you need more of this substance. It also works by decreasing the release of prolactin and growth hormone in the body, which treats diseases where you need less of these substances.

Bromocriptine may be used for:

- Stopping breast milk production for medical reasons only, and when you and your doctor have decided that it is necessary. Bromocriptine should not routinely be used to stop breast milk production. It should also not be used to relieve symptoms of painful breast engorgement after giving birth if these can be adequately treated with non-medical means (such as firm breast support, ice application) and/or a painkiller.
- Treating fertility and period problems usually caused by not having the right amount of prolactin. This includes polycystic ovary syndrome (reduces prolactin levels)
- Treating non-cancerous tumours in the brain called prolactinomas (reduces prolactin levels)
- Treating diseases where too much growth hormone is made, which causes people to be very tall or to have large hands and feet. This is called acromegaly (reduces growth hormone levels)
- Treating Parkinson's disease (increases dopamine levels).

#### **2. What you need to know before you take Bromocriptine**

**Do not take Bromocriptine if:**

- You are allergic to bromocriptine mesilate or other ergot alkaloids such as ergotamine
- You are allergic to any of the other ingredients in Bromocriptine (see Section 6)
- You have high blood pressure
- You have ever had blood pressure problems during pregnancy or after giving birth, such as eclampsia, pre-eclampsia, pregnancy-induced high blood pressure, high blood pressure after giving birth
- You have, or have ever had, heart disease, or other severe blood vessel disease
- You have, or have ever had, fibrotic reactions (scar tissue) affecting your heart
- You have, or have ever had, serious mental health problems
- You are breast-feeding.

If any of the above applies to you, talk to your doctor or pharmacist.

**Warnings and Precautions**

Talk to your doctor before taking Bromocriptine if

- You have just given birth as you may be more at risk of certain conditions. These are very rare but may include high blood pressure, heart attack, convulsions, stroke or mental problems. Therefore your doctor will need to check your blood pressure regularly during the first days of treatment. Speak immediately to your doctor if you experience high blood pressure, chest pain or unusually severe or persistent headache, with or without vision problems.
- You have, or have ever had stomach ulcers and bleeding
- You have liver disease
- You have, or have ever had a condition called fibrosis. Fibrosis causes thickening and stiffening of the heart, lungs and abdomen which can stop them working properly. Before you are given Bromocriptine your doctor will check that your heart, lungs and kidneys are in good condition. The doctor may also do an ultrasound (an echocardiogram) of your heart for check for scar tissue.
- You are pregnant or planning to become pregnant. If so, tell your doctor immediately.
- You have recently given birth, had a miscarriage or an abortion
- You have premenstrual problems or non-cancerous breast disease
- You have a non-cancerous tumour. You may need a full medical check-up first.
- You have Parkinson's disease

Do not give Bromocriptine to children under 7 years old.

**Take special care with Bromocriptine**

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, and abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

**Tell your doctor if you are taking any of the following medicines:**

- Any medicine used to change your blood pressure, such as diuretics ('water tablets'), beta blockers, calcium channel blockers or ACE inhibitors.
- Ergot alkaloids such as ergometrine (used to stop blood loss after giving birth) and ergotamine tartrate (used to treat migraines). This is especially important if you have just given birth or had an abortion

- Erythromycin or any other macrolide antibiotics (used to treat infections).
- Azole anti-fungals (used to treat fungal infections).
- Protease inhibitors (used to treat HIV).
- Octreotide (used to treat growth disorders).
- Antipsychotics such as phenothiazines, butyrophenones, thioxanthenes (used to treat mental disorders).
- Metoclopramide and domperidone (used to stop you feeling and being sick).
- Any other medicine, including medicines obtained without a prescription.

### **Taking Bromocriptine with food and drink**

You must take this medicine with a meal.

Avoid drinking alcohol as it may make the side effects of this medicine worse.

### **Pregnancy and breast-feeding**

Tell your doctor if you are pregnant or are planning to become pregnant.

You must not breast-feed. This medicine stops or slows down your breasts making milk.

Remember: Taking this medicine may increase or bring back your chances of getting pregnant. If you do not wish to get pregnant, ask your doctor for advice.

### **Driving and using machines**

You must not drive or operate machines if you feel dizzy or faint. This may mean you have low blood pressure. This is most likely to happen in the first few days. You may also feel very tired or suddenly fall asleep during the day whilst taking this medicine, if this happens you should not drive.

### **Bromocriptine tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **Bromocriptine tablets contain sodium**

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

## **3. How to take Bromocriptine**

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

### **Important:**

**Your doctor will choose the dose that is right for you or your child. The dose will be shown clearly on the label that your pharmacist puts on the medicine. If it does not, or you are not sure, ask your doctor or pharmacist.**

Remember: Always take this medicine with a meal.

### **Adults and Children between 7 and 17 years old:**

For most diseases, your doctor will start you or your child on a low dose of Bromocriptine and then gradually increase the dose as necessary. This will help the body adjust to the new medicine and stop you or your child from getting so many side effects. You should always follow the advice of your doctor about increasing the dose of the medicine.

As the dose changes, tablets and capsules may need to be taken together to get to the right dose. You may also need to break the tablets in half along the line down the middle. Your doctor or pharmacist will tell you how to do this. Never break the capsules in half.

The maximum dose for children aged 7-12 years is 5 to 10 mg, depending on the condition they are being treated for. The maximum dose for children aged 13-17 years is 20 mg.

If you are a woman, your doctor will advise you when in your menstrual cycle you should start to take this medicine.

### **The elderly:**

If you are elderly, your doctor may suggest you take a slightly lower dose than the usual adult dose. This is because you are more likely to have kidney, liver and heart problems or be taking other medicines, which will change how well bromocriptine works.

### **Patients with liver problems:**

Your doctor will tell you how much to take.

### **Medical check-ups**

When you are taking this medicine, your doctor may ask you to come for check-ups which may include:

- An ultrasound of your heart (an echocardiogram). This is to ensure that your heart is working properly and to check for fibrotic reactions. If fibrotic reactions occur, your doctor may stop your treatment with Bromocriptine.
- Blood pressure checks. This is important when you first start to take this medicine.
- If you are a woman and you have been taking Bromocriptine for a long time you may have six monthly gynaecological exams and cervical smear tests
- Eye sight checks
- If you are taking Bromocriptine for a disease involving a tumour, the size, shape and type of tumour may be checked regularly.

### **If you take more Bromocriptine than you should**

Do not take more Bromocriptine than you should. If you accidentally take too much of your medicine, immediately tell your doctor or go to the nearest hospital casualty department. Taking too much Bromocriptine may make you feel or be sick, have a fever or become abnormally tired.

### **If you forget to take Bromocriptine**

Do not take a double dose to make up for a forgotten dose. Simply take the next dose as planned.

### **If you stop taking Bromocriptine**

It is important to talk to your doctor if you want to stop taking your medicine. If you stop suddenly, you may get withdrawal symptoms including confusion, a reduced attention span and stiffness. If you have any further questions about taking this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, Bromocriptine can cause side effects, although not everybody gets them.

### **Seek immediate medical help if you have any of the following symptoms:**

- **You have a headache which does not go away, or is severe**
- **You get any problems with your eyesight after giving birth**
- **You feel faint, dizzy or have blurred vision**
- **You have blood in your stools. They may look black and tarry**
- **You vomit blood or dark particles that look like coffee granules**

- **You have severe pains in your stomach**
- **You have difficulty breathing, shortness of breath, swollen legs, chest or back pain.**

**Common:** may affect up to 1 in 10 people

- Headache
- Dizziness
- Drowsiness
- Feeling and being sick
- Constipation
- Blocked nose

**Uncommon:** may affect up to 1 in 100 people

- Restlessness
- Confusion or hallucinations
- Dry mouth
- Dizziness or light-headedness upon standing which may cause you to collapse (you may have low blood pressure)
- Leg cramps
- Itchy, red or swollen skin
- Hair loss
- Tiredness

**Rare:** may affect up to 1 in 1,000 people

- Extreme drowsiness
- Insomnia (trouble sleeping)
- Pins and needles
- Mental health problems
- Diarrhoea
- Inability to pass water and back pain
- Irregular heart beat including an abnormally slow or fast beating of the heart
- Lung problems that may cause difficulty breathing, a shortness of breath, pain when you breath in, or a cough that doesn't go away
- Swelling of the ankles
- Disturbed or blurred vision
- Watery discharge from your nose
- Ringing in your ears

**Very rare:** may affect up to 1 in 10,000 people

- Heart valve disorders such as inflammation or leaking of fluid in the heart - these may cause difficulty breathing, chest pains, weakness and swelling of the legs and ankles
- Extreme drowsiness during the day or falling asleep unexpectedly
- Pale or white fingers and toes, caused by cold temperatures.

**You may experience the following side effects:**

Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:

- strong impulse to gamble excessively despite serious personal or family consequences

- altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive
- uncontrollable excessive shopping or spending
- binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)

**Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.**

**If you have just given birth** you may be more at risk of certain conditions. These are very rare, but may include high blood pressure, heart attack, convulsion, stroke or mental problems.

### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 Bromocriptine**

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

Do not use Bromocriptine after the expiry date stated on the blister and carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light.

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 Bromocriptine contains**

The active substance is bromocriptine mesilate.

#### Bromocriptine 1 mg tablets

Each tablet contains 1 mg bromocriptine (as mesilate).

#### Bromocriptine 2.5 mg tablets

Each tablet contains 2.5 mg bromocriptine (as mesilate).

The other excipients are lactose monohydrate, maize starch, citric acid monohydrate, disodium edetate, maleic acid, silica colloidal anhydrous and magnesium stearate.

### **What Bromocriptine looks like and contents of the pack**

#### Bromocriptine 1 mg tablets

White to off-white, round, uncoated, flat faced beveled edge tablets debossed with “1” and “MG” on either side of break line on one face and plain on the other face, with an approximate diameter of 7.50 mm and thickness of 2.60 mm. The score line is not intended for breaking the tablet.

**Bromocriptine 2.5 mg tablets**

White to off-white, round, uncoated, flat faced beveled edge tablets debossed with “ML” on one face and break line on the other face, with an approximate diameter of 7.50 mm and thickness of 2.70 mm. The tablet can be divided into equal doses.

Bromocriptine tablets are available in blister pack.

**Pack size:**

Blister pack: 7, 10, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112 and 120 tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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