

Patient Information Leaflet

Bromocriptine 1 mg & 2.5 mg Tablets

Bromocriptine mesilate

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- In this leaflet, Bromocriptine 1 mg & 2.5 mg Tablets will be called Bromocriptine.

In this leaflet:

1. What Bromocriptine is for
2. Before you take Bromocriptine
3. How to take Bromocriptine
4. Possible side effects
5. How to store Bromocriptine
6. Further information

1. What Bromocriptine is 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. 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.

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.

Warnings about the ingredients in Bromocriptine

This medicine contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How To Take Bromocriptine

Always take Bromocriptine exactly as your doctor has told you.

Important:

Your doctor will choose the dose that is right for you. 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, the tablets 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.

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.

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