Package Information Leaflet

Bromocriptine 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 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.
- You have Parkinsons 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.

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.
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 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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Description	Bromocriptine 2,5mg
Component Type	Leaflet
Affiliate Item Code	2424841
Superceded Affiliate Item Code	56UK1781106-01
TrackWise PR No.	2424841
MA No.	PL 04569/1771
Packing Site/Printer	Madaus GmbH (Troisdorf - DE)
Supplier Code	707686
Other Local Codes:	56UK1781106-02
Sign-offs	

Date: 30/03/21 Time: 13:35

Pharma Code	373	No. of colours	1
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Trackwise Proof No.	P1	Equate CMYK with	
Client Market	United Kingdom		
Keyline/Drawing No.	824 WZ BPZ_ 148x297mm		
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3D Render ID	N/A	Dimensions	148 x 297 mm
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		Min Text Size used	7 pt

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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 side effects
(affect less than 1 in 10 people):
- Headache
- Dizziness
- Drowsiness
- Feeling and being sick
- Constipation
- Blocked nose.

Uncommon side effects
(affect less than 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 side effects
(affect less than 1 in 1000 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 side effects
(affect less than 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 or search for MHRA Yellow Card in the Google Play or Apply App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How To Store Bromocriptine

Keep out of the sight and reach of children.

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

Store the tablets below 25°C in the original package in order to protect from light.

Medicines should not be thrown away in waste water or in household waste. Return any medicine you no longer need to your pharmacist.

6. Further Information

What Bromocriptine contains
The active substance in Bromocriptine is bromocriptine mesilate
- Each 2.5 mg tablet contains 2.5 mg bromocriptine mesilate.
- The tablets also contain lactose, maize starch, disodium edetate, maleic acid, colloidal anhydrous silica, and magnesium stearate.
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free"

What Bromocriptine looks like
Bromocriptine 2.5 mg Tablets are round, white and marked with a groove on one side and '2.5 MG' on the other side. The tablets come in a blister strip containing 30 tablets or in an amber glass bottle containing 100 or 500 tablets.

Not all pack-sizes are marketed.

Marketing Authorisation Holder:
Mylan, Potters Bar, Hertfordshire, EN6 1TL, UK.

Manufacturer:
Meda Manufacturing GmbH, Neurather Ring 1, 51063 Cologne, Germany.

alternative:

Madaus GmbH, Lütticher Straße 5, 53842 Troisdorf, Germany.

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If this leaflet is difficult to see or read or you would like it in a different format, please contact Mylan, Potters Bar, Hertfordshire, EN6 1TL, UK.

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MA No.	PL 04569/1771	Keyline/Drawing No.	824 WZ BPZ_ 148x297mm								
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Sign-offs											

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