

Package leaflet: Information for the user

Parlodel 2.5 mg Tablets

Bromocriptine mesilate

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

1. WHAT PARLODEL TABLETS ARE AND WHAT IT IS USED FOR

Parlodel tablets contain the active ingredient bromocriptine, which belongs to a group of medicines called dopamine agonists and prolactin inhibitors.

Parlodel tablets are used for:

- Treatment of prolactinomas (a non-cancerous tumour of the pituitary gland in the brain).
- Co-treatment of acromegaly with surgery or radiotherapy. Acromegaly is abnormal growth caused by high levels of growth hormone.
- Treatment of hyperprolactinaemia (abnormally high level of prolactin in the blood) in men with hypogonadism (a low sperm count, lack of sex drive and inability to achieve an erection) and/or galactorrhoea (unexplained milk secretion).
- Treatment of hyperprolactinaemia (abnormally high level of prolactin in the blood) in women with hypogonadism (infrequent periods, hot flushes, vaginal dryness), irregular periods, infertility and/or galactorrhoea (unexplained milk secretion).
- To prevent lactation (milk production) for medical reasons.
- Stopping breast milk production for medical reasons only, and when you and your doctor have decided that it is necessary. Bromocriptine should not be routinely 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.
- Treatment of Parkinson's disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARLODEL TABLETS

Do not take Parlodel tablets:

- If you are allergic to bromocriptine, other similar drugs, or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- If you have high blood pressure

- If you have or ever have had blood pressure problems caused by pregnancy or after giving birth such as eclampsia, pre-eclampsia, pregnancy-induced high blood pressure, high blood pressure after giving birth
- If you have or have ever had heart disease or severe blood vessel disease
- If you have or have ever had serious mental health problems
- If you will be treated with Parlodel for a long period and have or had fibrotic reactions (scar tissue) affecting your heart

Warnings and precautions

Talk to your doctor or pharmacist before taking Parlodel tablets if you have any of the following conditions:

- A history of stomach ulcers
- Severe headache
- Visual disturbances
- You have given birth within the last 6 weeks
- You become pregnant
- You are taking a drug that alters blood pressure, e.g. drugs that prevent bleeding
- You develop a cough, respiratory infection, or chest pain
- You develop back pain
- You have swollen legs
- You have kidney problems, e.g. difficulty urinating

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. 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).

Take special care with Parlodel

- If you have or had fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with Parlodel for a long period, your physician will check before starting treatment whether your heart, lungs and kidneys are in good condition. He/she will also have an echocardiogram (an ultrasound test of the heart) before treatment is started. During treatment your physician will pay special attention to any signs which may be related to fibrotic reactions. If necessary he/she will have an echocardiogram taken. If fibrotic reactions occur treatment will have to be discontinued.
- 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, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

Children

Children under 7 years of age should not take Parlodel tablets.

Other medicines and Parlodel tablets

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

If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed. Tell your doctor or pharmacist if you are taking:

- Azole anti-fungals (used to treat fungal infections)
- HIV (AIDS) treatments such as ritonavir
- Antibiotics such as erythromycin or josamycin
- Octreotide (used to treat cancer e.g. of the pancreas)

- Treatments for mental illness
- Metaclopramide (used to treat digestive tract disorders)
- Domperidone (used to prevent nausea and vomiting)
- Alcohol (may increase side effects)
- Ergot alkaloids such as ergotmetrine or methylergometrine (treatments for migraine)
- Antipsychotics such as phenothiazines, butyrophenones, and thioxanthenes (used to treat mental disorders).

It may still be all right for you to be given Parlodel tablets and your doctor will be able to decide what is suitable for you.

Parlodel tablets with food and alcohol

You must take this medicine with a meal. Avoid drinking alcohol as it may make the side effects of this medicine worse.

Pregnancy, Breast-feeding and Fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide whether or not you should be given Parlodel tablets.

Parlodel prevents lactation therefore it should not be given while breast-feeding.

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

Parlodel tablets may cause sudden sleepiness and reduced alertness without warning. They may also reduce your blood pressure and make you dizzy. You should not drive or operate machines during treatment with Parlodel tablets.

Parlodel tablets contain lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Parlodel tablets.

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

3. HOW TO TAKE PARLODEL 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. The dose of Parlodel depends on the condition for which it is being used. Parlodel tablets should always be taken during a meal.

Medical check-ups to be carried out during treatment.

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

The usual doses are as follows:

Therapy is usually started gradually to keep side effects to a minimum. This is achieved by taking Parlodel in the following manner;

To start with, half a tablet (1.25 mg) at bedtime. After 2 to 3 days the dose is increased to 2.5 mg (one tablet) at bedtime. Dosage may then be increased by half to one tablet every 2 to 3 days until a dose of 2.5 mg twice daily. If the dose is to be increased, it will be done in a similar way.

Elderly

There is no dosage adjustment required for the elderly patients.

Paediatric population

Prescribing of Parlodel in children and adolescents (aged 7 to 17) should be limited to Paediatric Endocrinologists.

This medicine is not suitable for children under the age of 7 years.

If you take more Parlodel tablets than you should

Contact your doctor straight away. Signs of overdose are feeling sick, vomiting, dizziness, dizziness on standing, fast heart rate, sleepiness, tiredness and hallucinations (hearing or seeing things).

If you forget to take Parlodel tablets

Take it as soon as you remember, but do not take it less than 4 hours before your next dose. Remember to take it with food.

If you stop taking Parlodel tablets

Dosage should be reduced and discontinued gradually. Rapid withdraw of the medicine may cause withdrawal syndrome (including anxiety, depression, fatigue, sweating, pain, etc.).

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.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

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

- If you have a headache which does not go away, or is severe
- If you get any problems with your eyesight after giving birth
- If you feel faint, dizzy or have blurred vision
- If you have blood in your stools. They may look black and tarry
- If you vomit blood or dark particles that look like coffee granules
- If you have severe pains in your stomach
- If you have difficulty breathing, shortness of breath, swollen legs, chest or back pain.

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

Other possible side effects:

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
- Dyskinesia (involuntary movements)
- Psychomotor agitation

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 breathe 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
- Abdominal pain
- Retroperitoneal fibrosis (a thickening of the abdominal lining that can cause obstruction of the urinary tract)
- Gastrointestinal ulcer
- Gastrointestinal bleeding

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

- Cardiac valvulopathy and related disorders e.g. inflammation (pericarditis) or leaking fluid in the pericardium (pericardial effusion). The early symptoms may be one or more of the following: difficulty breathing, shortness of breath, chest or back pain and swollen legs. If you experience any one of these symptoms you must tell your doctor immediately.
- Extreme drowsiness during the day or falling asleep unexpectedly
- Pale or white fingers and toes, caused by cold temperatures
- A syndrome resembling Neuroleptic Malignant Syndrome (a reaction to some medicines with a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure, which may lead to coma) on abrupt withdrawal of Parlodel.

Not known: (cannot be estimated from the available data)

- Drug withdrawal syndrome (including apathy, anxiety, depression, fatigue, sweating, pain, etc)

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, seizures, stroke or mental problems.

If you are taking Parlodel for Parkinson's disease you may get an urge to gamble, have an abnormally high sex drive or a changed sexual interest. Please talk to your doctor if you feel any of these effects, they may need to change your dose.

If you get any side effects, any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARLODEL 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 original container and blister after 'EXP'. The expiry date refers to the last day of that month.

Store below 25°C in original package. Keep blister in the outer carton.

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 Parlodel tablets contain

Each tablet contains 2.5 mg of the active ingredient bromocriptine mesilate.

The other ingredients are: lactose monohydrate, maize starch, disodium editate, maleic acid, colloidal anhydrous silica and magnesium stearate.

What Parlodel tablets look like and contents of the pack

Whitish, round, flat, bevelled edge, angle-scored and coded "2.5 MG" on upper side. Parlodel tablets come in blister packs containing 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
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Manufacturer

MADAUS GmbH,
51101 Cologne,

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