

Package leaflet: Information for the user

Parlodel

5 mg Hard Capsules

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.

The name of your medicine is Parlodel 5 mg hard capsules, which will be called Parlodel capsules throughout this leaflet.

What is in this leaflet:

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

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

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

Parlodel capsules are used for:

- Treatment of Parkinson's disease
- 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 levels of prolactin causing unexplained milk secretion and irregular periods in women and lack of sex drive in men).
- Treatment of menstrual cycle disorders and female infertility caused by hyperprolactinaemia (see above).

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

Do not take Parlodel capsules:

- 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 uncontrolled high blood pressure
- If you have heart disease
- If you have or have had, a serious mental illness
- If you have severe blood vessel disease
- 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 capsules 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

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 15 years of age should not take Parlodel capsules.

Other medicines and Parlodel capsules

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

If you take these capsules with some other medicines, the effect of these capsules 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 capsules and your doctor will be able to decide what is suitable for you.

Parlodel capsules 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 you think you may be pregnant, you should inform your doctor who will decide whether or not you should be given Parlodel capsules.

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.

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.

Driving and using machines

Parlodel capsules 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 capsules.

Parlodel capsules contain lactose

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

3. HOW TO TAKE PARLODEL CAPSULES

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

Parlodel capsules should always be taken during a meal.

Medical check-ups to be carried out during treatment.

The dose of Parlodel capsules depends on the condition for which it is being used. It may be needed to start your treatment with Parlodel tablets to get the appropriate low starting doses. For higher doses, Parlodel capsules are preferable to use.

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. 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 usual doses are as follows:

Adults and older people

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

Initially half a tablet (1.25mg) at bedtime, increasing after 2 to 3 days to 2.5 mg at bedtime. Dosage may then be increased by half to one tablet at 2 to 3 day intervals, until a dosage of 2.5mg twice daily is reached. If the dose is to be increased, it will be done in a similar way.

To do this, use Parlodel 2.5 mg tablets as these tablets can be cut in half. When using a dose of 5 mg or higher it is preferable to use Parlodel capsules. The dose of Parlodel that you take after this gradual start will depend on the condition that the doctor is treating you for, so always follow the doctor's instructions carefully. The label on your medicines should tell you how much medicine to take and when to take it.

If it does not, or if you are not sure, ask your doctor or pharmacist.

If you take more Parlodel capsules 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 capsules

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 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.

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 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARLODEL CAPSULES

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 to protect from light and moisture.

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 capsules contain:

Each capsule contains 5 mg of the active ingredient bromocriptine mesilate.

Capsule contents: lactose monohydrate, maize starch, maleic acid, colloidal anhydrous silica and magnesium stearate.

Capsule shell: gelatin, titanium dioxide (E171) and indigo carmine (E132).

Printing Ink: iron Oxide Black (E172) and shellac.

What Parlodel capsules look like and contents of the pack

Parlodel is a hard capsule with a light blue cap and white body printed “5mg” in ink on one side. Parlodel capsules come in blister packs containing 30 or 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoye Industrial Estate,
Dublin 13,
Ireland

Manufacturer

MEDA Manufacturing GmbH,
Neurather Ring 1,
51063 Köln, Germany

This leaflet was last revised in August 2018