

Parlodel(R)

bromocriptine mesylate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Parlodel.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Parlodel against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Parlodel is used for

Parlodel has several uses. It can be used:

1. to prevent the production of breast milk (lactation) in women who cannot breast-feed for medical reasons. If breast milk production has already begun, your doctor can advise you about other methods of stopping lactation
2. to treat people who have high blood levels of a hormone called prolactin. This condition is sometimes caused by a type of tumour called a prolactinoma
3. to treat acromegaly, a disease in which the body produces too much growth hormone. Parlodel treats this disease by reducing the level of growth hormone in the blood
4. in people with Parkinson's disease to relieve symptoms such as shaking of the limbs, stiffness and slowness of movement. Parlodel is often used in combination with other medicines such as levodopa.

Parlodel contains the active ingredient, bromocriptine. It belongs to a group of medicines known as the ergot alkaloids.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend this medicine for children.

Before you take Parlodel

When you must not take it

Do not take Parlodel if you have an allergy to:

- * bromocriptine (the active ingredient) or any of the other ingredients of Parlodel listed at the end of this leaflet
- * any other medicines containing ergot alkaloids.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Parlodel if you have any of the following medical conditions:

- * high blood pressure that is not controlled
- * toxemia during pregnancy or immediately after giving birth, with symptoms such as high blood pressure, fluid buildup and convulsions
- * severe heart disease
- * mental illness now or in the past

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Do not take Parlodel after the expiry date printed on the pack or

if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have any of the following health problems / medical conditions:

- * diabetes
- * problems with your liver
- * stomach problems such as ulcers
- * problems with blood circulation

Your doctor may want to take special precautions if you have any of the above conditions.

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

Your doctor can discuss with you the benefits and any risks of taking this medicine during pregnancy.

Tell your doctor if you are breast-feeding or intend to breast-feed.

Parlodel prevents the production of breast-milk due to its effects on prolactin.

Tell your doctor if you are lactose intolerant.

This medicine contains lactose.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Parlodel may interfere with one another. These include:

- * other medicines containing ergot alkaloids, such as medicines used to treat migraine headaches
- * medicines used to treat high

blood pressure

- * any other medicine that may either raise or lower blood pressure
- * levodopa, a medicine for Parkinson's disease
- * some antibiotics such as erythromycin
- * octreotide, a medicine used to treat acromegaly and certain tumours

You may need to take different amounts of your medicines or to take different medicines while you are taking Parlodel. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take Parlodel

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Parlodel is available as 2.5 mg tablets and as 5 mg and 10 mg capsules.

Doses above 10 mg per day are usually taken in the form of capsules.

The dose that your doctor prescribes will depend on your condition.

1. To prevent breast milk production, one tablet is taken twice daily for 2 weeks. Sometimes milk production will start again 2 or 3 days after the medicine is finished. A further 1 week course of Parlodel will usually bring this under control.
2. To lower prolactin levels, treatment usually starts with half a tablet two to three times a day

If necessary, this dose may be gradually increased to one tablet three times each day. If the high prolactin levels are caused by a prolactinoma, the dose may be increased up to 15 mg daily, usually divided into 2 to 4 doses.

3. For acromegaly, treatment usually starts with half a tablet each night. The dose is then slowly increased over a period of 1 to 2 weeks to one tablet four times a day. The dose can be further increased if needed. Most people need between 10 mg and 30 mg per day. The maximum dose is not usually more than 40 mg per day.
4. For Parkinson's disease, treatment usually starts with half a tablet once or twice a day for the first week. The dose may be increased by half a tablet per week until the best effect is achieved. Most people need between 5 mg and 40 mg per day in 3 or 4 divided doses.

How to take it

When you start to take Parlodel, take the first dose with a snack just before bedtime. After you start taking the medicine, be careful to get up slowly from a sitting or lying position.

Parlodel can make you dizzy, lightheaded or faint, especially when you first take it. This is because your blood pressure has suddenly dropped. Taking the first dose at bedtime and being careful when standing up will help your body get used to the change in blood pressure and will reduce the risk of falling.

After the first dose of Parlodel, take the tablets or capsules at mealtime with a full glass of water.

Taking Parlodel with food helps to reduce stomach irritation and nausea.

Take the medicine at about the same time each day.

Taking the doses at the same time each day will have the best effect. It will also help you to remember to

take them.

How long to take it

Continue taking Parlodel for as long as your doctor recommends.

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Parlodel. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Some of the symptoms of an overdose may include nausea, vomiting, sleepiness, dizziness, lightheadedness, hallucinations (seeing or hearing things that are not there).

While you are taking Parlodel

Things you must do

If you are taking Parlodel to lower prolactin levels and you do not wish to become pregnant, you must use a reliable means of contraception.

As your prolactin levels become lower, your menstrual periods may return to normal and you could become pregnant.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to do some tests from time to time to make sure the treatment is working and to prevent unwanted side effects from happening.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Parlodel.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Parlodel.

Things you must not do

Do not give this medicine to anyone else even if their condition seems similar to yours.

Do not take it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Parlodel affects you.

This medicine may make you feel dizzy, lightheaded or faint, especially when you first take it. It may also cause confusion and mental changes in a few people. Very rarely it can cause extreme sleepiness and sudden onset of sleep in the middle of daytime activities, sometimes without warning. If you have any of

these symptoms, do not drive or do anything else that could be dangerous.

Be careful when drinking alcohol while taking Parlodel.

The combination may cause unwanted side effects. Your tolerance for alcohol may be lower than usual.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Parlodel.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Some of the side effects listed below are more common at the beginning of treatment and may disappear as treatment continues. Your doctor may be able to reduce some side effects by lowering your dose of Parlodel.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- * nausea or vomiting
- * dizziness or lightheadedness, especially on standing up
- * drowsiness or sleepiness (if you have extreme sleepiness or sudden onset of sleep in the middle of daytime activities, tell your doctor immediately)
- * headache
- * tiredness
- * sinus congestion
- * constipation
- * diarrhoea
- * nervousness

- * difficulty sleeping
- * feeling unsteady on your feet
- * depression (sad mood)
- * loss of appetite
- * dry mouth, metallic taste
- * sore eyes or blurred vision
- * hair loss
- * burning sensation in the breasts
- * leg cramps or burning feeling in the feet
- * painful, tingling or pale fingers and toes when exposed to cold
- * buzzing, hissing, whistling, ringing or other persistent noise in the ears
- * uncontrolled body movements
- * irregular heart beat
- * stomach pain
- * swelling due to fluid buildup
- * skin rash or itchiness
- * behavioural changes such as urge to gamble or increased sexual desire urges

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if:

- * you develop severe persistent headache or vision problems. Some women who have taken Parlodel to prevent breast milk production have had seizures (fits), high blood pressure, stroke, heart attack, or mental disorders. It is not known whether these problems are caused by Parlodel or are complications of giving birth.
- * you notice any signs of stomach bleeding such as red or black bowel motions, bloody diarrhoea, bleeding from the back passage or vomiting blood. Some people being treated with high doses of Parlodel for acromegaly have had serious stomach bleeding.
- * you develop confusion, changes in behaviour, hallucinations (seeing or hearing things that are not there) or sudden sleep attacks. Some people being treated with Parlodel for Parkinson's disease, especially with high doses, have experienced mental changes.

- * you develop wheezing, cough or other breathing problems, chest pain, back pain, swelling of the feet or kidney problems while taking Parlodel. When Parlodel is used for a long time to treat Parkinson's disease, it can affect the lungs, heart or abdomen. Your doctor may ask you to have regular chest x-rays to see if you are developing any problems.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After using Parlodel

Storage

- * Keep your medicine in the original container until it is time to take it
- * Store it in a cool dry place.
- * Do not store Parlodel or any other medicine in the bathroom or near a sink.
- * Do not leave it in the car or on window sills.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Parlodel or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Parlodel 2.5 mg tablets are round white scored tablets marked with "XC" on one side and "SANDOZ" on the other side; packs of 30 or 60 tablets.

Parlodel 5 mg capsules are pale blue and white capsules printed with "PS" in brown; packs of 60 capsules.

Parlodel 10 mg capsules are large white unmarked capsules; packs of 100 capsules.

Ingredients

Parlodel tablets contain 2.5 mg of the active ingredient, bromocriptine (as the mesylate salt). They also contain:

- * magnesium stearate
- * silica colloidal anhydrous
- * maize starch
- * disodium edetate
- * maleic acid
- * lactose

Parlodel capsules contain 5 mg or 10 mg of the active ingredient, bromocriptine (as the mesylate salt). They also contain:

- * magnesium stearate
- * silica colloidal anhydrous
- * maize starch
- * maleic acid
- * lactose
- * gelatin
- * titanium dioxide.

The 5 mg capsule shell contains:

- * shellac
- * red iron oxide CI77491
- * indigo carmine CI73015

Parlodel does not contain gluten, tartrazine or any other azo dyes.

Sponsor

Parlodel is supplied in Australia by:
NOVARTIS Pharmaceuticals
Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone 1 800 671 203

(R) = Registered Trademark

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2.5 mg tablet bottle AUST R 13340
5 mg capsule AUST R 13365
10 mg capsule AUST R 13366