

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Parlodel?

Parlodel contains the active ingredient bromocriptine. Parlodel is used to for the following: for the following:

- Prevention/suppression of breast milk production (lactation) in women who cannot/do not breast feed for medical reasons.
- Treatment of people who have high blood levels of a hormone called prolactin.
- Treatment of acromegaly, a disease in which the body produces too much growth hormone.
- To relieve symptoms, such as shaking of the limbs, stiffness and slowness of movement, in people with Parkinson's disease. Parlodel is often used in combination with other medicines such as levodopa.

For more information, see Section [1. Why am I using Parlodel?](#) in the full CMI.

2. What should I know before I use Parlodel?

Do not use if you have ever had an allergic reaction to bromocriptine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use Parlodel?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Parlodel and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Parlodel?

The dose that your doctor prescribes will depend on your condition. Follow all directions given to you by your doctor and pharmacist carefully.

More instructions can be found in Section [4. How do I use Parlodel?](#) in the full CMI.

5. What should I know while using Parlodel?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Parlodel.• Do not use Parlodel if you are breast feeding.• 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.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• 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.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking Parlodel. The combination may cause unwanted side effects. Your tolerance for alcohol may be lower than usual.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Protect from light.

For more information, see Section [5. What should I know while using Parlodel?](#) in the full CMI.

6. Are there any side effects?

Common side effects: nausea, vomiting, dizziness or lightheadedness on standing up, drowsiness/sleepiness, tiredness, sinus congestion, diarrhoea, constipation, nervousness, feeling unsteady on your feet, sad mood, difficulty sleeping or restlessness.

Severe side effects: severe persistent headache or vision problems, red/black bowel motion, bloody diarrhoea, hallucinations. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Parlodel®

Active ingredient(s): *bromocriptine (as mesilate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Parlodel. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Parlodel.**

Where to find information in this leaflet:

- [1. Why am I using Parlodel?](#)
- [2. What should I know before I use Parlodel?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Parlodel?](#)
- [5. What should I know while using Parlodel?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Parlodel?

Parlodel contains the active ingredient bromocriptine. Parlodel belongs to a group of medicines known as the ergot alkaloids, derived from a type of fungus.

Parlodel is used for the following medical conditions:

- Prevention/suppression of breast milk production (lactation) in women who cannot/do not breast feed for medical reasons. If breast milk production has already begun, your doctor can advise you about other methods of stopping lactation.
- Treatment of people who have high blood levels of a hormone called prolactin. This condition is sometimes caused by a type of tumour called prolactinoma.
- Treatment of 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.
- To relieve symptoms, such as shaking of the limbs, stiffness and slowness of movement, in people with Parkinson's disease. Parlodel is often used in combination with other medicines such as levodopa.

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.

2. What should I know before I use Parlodel?

Warnings

Do not use Parlodel if:

- you are allergic to bromocriptine, other medicines containing ergot alkaloids, or any of the ingredients

listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- Some 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
- you have the following medical conditions:
 - high blood pressure that is not controlled (uncontrolled hypertension)
 - toxemia during pregnancy or immediately after giving birth, with symptoms such as high blood pressure, fluid build-up and convulsions
 - severe heart disease
 - mental illness now or in the past
- the package is torn or shows signs of tampering

Check with your doctor if you:

- have any other medical conditions:
 - diabetes
 - problems with your liver
 - black stools or stomach ulcers
 - problems with blood circulation
 - excessive drowsiness, or if you unexpectedly fall asleep
- take any medicines for any other condition
- are lactose intolerant as this medicine contains lactose
- are allergic to any other medicines, foods, dyes or preservatives.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Use in the Elderly

Parlodel may be used with caution in older people.

Use in Children

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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 and post-delivery bleeding
- 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, used to treat infections, such as erythromycin
- octreotide, a medicine used to treat acromegaly and certain tumours
- medicines used to treat HIV/AIDS, such as ritonavir, nelfinavir, indinavir, and delavirdine.
- medicines used to treat fungal infections such as ketoconazole, itraconazole, and voriconazole.
- dopamine antagonists, such as phenothiazines, butyrophenones thioxanthenes, metoclopramide, and domperidone.
- phenylpropanolamine (a medicine used to treat nasal congestion)
- bromocriptine, a medicine used to treat Parkinson's disease
- sumatriptan, a medicine used to treat migraine
- ergot alkaloids, medicines used to treat migraine and post-delivery bleeding.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Parlodel.

4. How do I use Parlodel?

How much to take

- Follow all directions given to you by your doctor and pharmacist carefully. The dose that your doctor prescribes will depend on your condition.
- 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.
- 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.

- 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.
- 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.

When to take Parlodel

- Parlodel should be taken at about the same times each day.
- Taking the doses at the same times each day will have the best effect. It will also help you to remember to take them.

How to take Parlodel

- **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 at mealtime with a full glass of water.**
Taking Parlodel with food helps to reduce stomach irritation and nausea.

How long to take Parlodel

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 use Parlodel

Parlodel should be used regularly at the same times each day.

If it is almost time for your next dose, skip the dose you missed and take your 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 dose 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 use too much Parlodel

If you think that you have used too much Parlodel, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using Parlodel?

Things you should do

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 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.

Call your doctor straight away if you:

- are pregnant

Remind any doctor, dentist or pharmacist you visit that you are using Parlodel.

Things you should not do

- **Do not use Parlodel if you are breast feeding.** Women who have taken Parlodel after childbirth or abortion have experienced some rare, serious side effects. These include fits, high blood pressure, stroke, heart attack and mental disorders.
- **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

Tell your doctor or caregiver if you notice any unusual behavioural changes.

Some impulse control disorders have been reported in patients treated with high doses of this medicine. These may include an increased sexual drive, a failure to control gambling, or failure to resist temptation, urge, or impulse.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Protect from light.

Store it in a cool dry place below 25°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: <ul style="list-style-type: none">• nausea or vomiting• constipation• diarrhoea• heartburn, recurrent stomach pain	Speak to your doctor if you have any of these less serious side effects and they worry you.

<p>Nervous system related:</p> <ul style="list-style-type: none"> dizziness or light headedness, 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) severe, progressive, or persistent headaches <p>Lungs related:</p> <ul style="list-style-type: none"> unexplained shortness of breath or difficulty breathing sinus congestion <p>General disorders:</p> <ul style="list-style-type: none"> tiredness nervousness swelling of the arms or feet due to fluid build up <p>Brain related:</p> <ul style="list-style-type: none"> difficulty sleeping or restlessness physical excitement or muscular activity associated with anxiety or mental tension (such as pacing, tapping of feet, or another repeated action) depression (sad mood) strange or disturbing thoughts or moods behavioural changes such as self-harm, urge to gamble, failure to resist a temptation or impulse, or increased sexual drive <p>Musculoskeletal related:</p> <ul style="list-style-type: none"> feeling unsteady on your feet leg cramps or burning feeling in the feet uncontrolled body movements (such as uncontrollable twitching, jerking or writhing) <p>Others:</p> <ul style="list-style-type: none"> loss of appetite dry mouth, metallic taste hair loss burning sensation in the breasts painful, tingling or pale fingers and toes when exposed to cold buzzing, hissing, whistling, ringing or other persistent noise in the ears an irregular, slow, or fast heart beat sudden watery discharge from your nose skin rash or itchiness 	
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<ul style="list-style-type: none"> lower back pain, swollen legs and pain when passing urine sore eyes or blurred vision 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> 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. 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. confusion, 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. muscle stiffness, agitation, very high fever, or heart problems. wheezing, cough or other breathing problems, chest pain, back pain, swelling of the feet or kidney problems while taking Parlodel. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Parlodel contains

Active ingredient (main ingredient)	bromocriptine (as mesilate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• magnesium stearate• silica colloidal anhydrous• maize starch• disodium edetate• maleic acid• lactose
Potential allergens	sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What Parlodel looks like

Parlodel 2.5 mg – round white scored tablets marked with "XC" on one side and "SANDOZ" on the other side. Pack size of 30 tablets (Aust R 13367).

Who distributes Parlodel

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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