

# DOPERGIN<sup>®</sup> (Doe-PER-gin)

*lisuride hydrogen maleate*

0.2mg tablets

---

## What is in this leaflet

---

This leaflet answers some common questions about Dopergin. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

**Keep this leaflet with the medicine.** You may need to read it again.

---

## What is Dopergin used for and how does it work

---

### *What is Dopergin used for?*

Dopergin is used in the management of the symptoms of Parkinson's disease.

Dopergin is also used to control the production and flow of breast milk (lactation) where medically indicated, an over-production of growth hormone (acromegaly) and other prolactin-induced conditions such as absence of menstruation (amenorrhoea), infertility in women and pituitary tumours.

### *How does Dopergin work?*

Dopergin tablets contain the active ingredient lisuride hydrogen maleate, which belongs to a group of medicines called dopamine agonists. Parkinson's disease is caused by the brain not making enough of a chemical called dopamine, which controls muscle movement. It works by improving the effect of dopamine in the brain and helps reduce the symptoms of Parkinson's disease.

Dopergin is sometimes prescribed with medicines containing levodopa. These two medicines work together so that it is possible to take lower doses of each.

Dopergin also suppresses the hormone, prolactin. Prolactin is produced by the pituitary gland in the brain and is involved in the production and flow of breast milk.

High levels of prolactin can also prevent the normal function of the ovaries. Absence of menstruation and infertility can be treated with Dopergin if they are caused by high levels of prolactin.

In addition, high prolactin levels and absence of menstruation can also be caused by pituitary tumours. In large benign tumours (macroadenomas), Dopergin can improve the symptoms and reduce the size of the tumour.

**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.

---

## Before you take Dopergin

---

### ***When you must not take it***

#### **Do not take Dopergin:**

- if you are allergic to lisuride hydrogen maleate, the active ingredient in Dopergin; any of the ingredients listed at the end of this leaflet or any similar medicine such as other ergot derivatives
- if you are taking any cough or cold medicines containing phenylpropanolamine
- if you have a severe disorder affecting the circulation of blood in your arteries to the body and/or heart

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 this medicine after the expiry date printed on the bottle.** The expiry date is printed on the carton and on the bottle label after “EXP” (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

**Do not take this medicine if the packaging is torn or shows signs of tampering.** If the packaging is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### ***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- a history of or currently have severe mental illness
- high blood pressure, heart disease, seizures or stroke
- liver or kidney disease
- problems with blood circulation throughout the body and to the heart

**Tell your doctor if you are pregnant or intend to become pregnant.** Like most medicines of this kind, Dopergin is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.

It is recommended that when Dopergin has been prescribed for you for the treatment of infertility, Dopergin should be stopped as soon as pregnancy is suspected. If pregnancy is not desired, contraception must be used.

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

**If you have not told your doctor about any of the above, tell them before you start taking Dopergin.**

**Dopergin contains lactose.** If you have been told that you have an intolerance to some sugars, contact your doctor before taking it.

### ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.** Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking Dopergin because its effect may be increased.

Some medicines may interfere with Dopergin. These include:

- medicines used to treat mental illness
- other ergot alkaloids (e.g. methyl ergometrin)
- medicines which have sedative effects
- other medicines used in the treatment of Parkinson's disease
- medicines for controlling blood pressure (particularly for women)

These medicines may be affected by Dopergin or may affect how it works. You may need different amounts of your medicines, or you may need to take different medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist before you take Dopergin.**

---

## **How to take Dopergin properly**

---

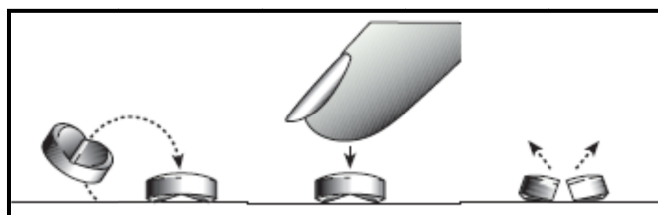
**Follow all directions given to you by your doctor or pharmacist carefully.** They may differ from the information contained in this leaflet.

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

### ***When and how much to take***

Swallow the tablets whole with a full glass of water. Take Dopergin with a meal or snack, preferably in the evening.

To halve a 0.2 mg Dopergin tablet, place the tablet on a hard surface with the scored side facing down, then press with one finger (see following diagram).



**If you think that the effect of Dopergin is too strong or too weak, talk to your doctor or pharmacist.**

Unless otherwise instructed by your doctor, the following dosage guidelines apply:

***Parkinson's disease***

Your doctor will adjust the dose for your individual requirements.

Treatment begins with 0.1 mg (half a tablet) in the evening. Your doctor will gradually increase your dose over several weeks. Your doctor may also prescribe you other anti-parkinson medicines to take with Dopergin.

***Suppression of the normal production and flow of breast milk, only when medically indicated***

Treatment with Dopergin should begin immediately after or within the first 24 hours of delivery or abortion.

0.2 mg should be taken 2 to 3 times daily for 14 days.

***Excessive or spontaneous breast milk flow, prolactin-induced absence of menstruation and prolactin-induced infertility in women, over production of growth hormone***

The treatment of excessive or spontaneous breast milk flow must be continued until the breast milk flow has completely stopped.

For prolactin-induced absence of menstruation, your doctor will determine the duration of use, but you must continue taking Dopergin until normal cycles with regular menstrual periods is restored.

Treatment is 0.1 mg (half a tablet) in the evening, increasing by half a tablet daily for 3 days. Maximum 0.3 mg (one and a half tablets) daily.

For the treatment for the over production of growth hormone, the dose can be increased to a maximum 2 mg (10 tablets) daily.

**Continue taking your medicine for as long as your doctor tells you.** This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

***If you forget to take it***

**If you forget to take one or more of your Dopergin tablets, take your next tablet at the normal time it is due.**

**Do not take a double dose to make up for forgotten individual doses.** This may increase the chance of you getting an unwanted side effect.

**If you are unsure what to do, ask your doctor or pharmacist.**

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

---

## While you are taking Dopergin

---

### *Things you must do*

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

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**While weaning your baby from the breast, do not put your baby to the breast or pump off breast milk.** By controlling the production of breast milk, mastitis (bacterial infection of the breast) can be managed. For severe infections, your doctor may prescribe you antibiotics for treatment.

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.

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

**Your doctor will need to do some tests from time to time to detect any changes to your heart, lungs or kidneys.** These tests include chest x-rays, physical examinations, blood tests and heart monitoring. Your doctor will repeat these tests regularly while you are on Dopergin.

### *Things you must not do*

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

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.** If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

### *Things to be careful of*

**Be careful driving or operating machinery until you know how Dopergin affects you.** Particularly at the beginning of treatment, Dopergin can occasionally lead to a sudden fall in blood pressure that may impair your ability to drive or to operate machinery. Some people may also experience drowsiness and/or sudden onset of sleep. If you have any of these symptoms, do not drive or operate machinery or do anything else that could be harmful.

**Alcohol should be avoided while you are taking this medicine.** If you drink alcohol, it may enhance the effects of Dopergin and cause drowsiness.

**Tell your doctor if you notice changes in your behaviour that result in a strong desire to gamble or an increase in your sexuality.** This has been reported in patients treated with dopamine for Parkinson's disease, including Dopergin.

---

## **Side Effects**

---

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

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

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- decreased or loss of appetite
- uncontrollable movements, twitching or muscle spasms
- drowsiness
- dizziness or spinning sensation, light-headedness when getting up quickly
- headache
- cold hands or feet
- nausea, vomiting
- dry mouth
- severe constipation
- swelling of hands, ankles or feet
- sweating
- hallucinations, feeling anxious, confusion, nightmares, trouble sleeping

The above list includes the common side effects of your medicine. They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- fast or irregular heart beats
- burning pain, redness in the hands or feet
- paranoid reactions

The above list includes serious side effects that may require medical attention.

**If any of the following happen, stop taking Dopergin and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- signs of an allergy such as rash; itching or hives on the skin; swelling of the face; lips, tongue or other parts of the body; shortness of breath, wheezing or trouble breathing
- chest pain, persistent urge to cough
- seizures, fits or convulsions
- dull stomach pain that increases with time

These very serious side effects are rare. If you have these side effects you may need urgent medical attention.

Other reported side effects include compulsive behaviours such as increased urge to gamble, increased libido and increased sexuality. These side effects go away when either treatment is stopped or the dose is reduced. Appropriate help and support should be sought via your doctor, carers if needed.

Your doctor may monitor your blood pressure from time to time as Dopergin may increase your blood pressure.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.** Other side effects not listed above may also occur in some people.

---

## **In case of overdose**

---

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Dopergin.** You may need urgent medical attention.

**Do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose may include nausea, vomiting and dizziness.

---

## **Storage conditions**

---

**Keep your tablets in the bottle until it is time to take them.**

If you take the tablets out of the bottle they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C and protect from light.**

**Do not store it or any other medicine in the bathroom, near a sink or on a window sill.**

**Do not leave it in the car.** Heat and dampness can destroy some medicines.

**Keep it 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

**Return any unused medicine to your pharmacist.**

---

## Product Description

---

### *What it looks like*

Dopergin 0.2 mg tablets are white, round tablets, with a deep, v-shaped score on one side.

### *Ingredients*

Active ingredient:

- Dopergin – 0.2 mg lisuride hydrogen maleate per tablet

Inactive ingredients:

- lactose
- microcrystalline cellulose
- magnesium stearate
- tartaric acid
- sodium calcium edetate

---

## Sponsor Details

---

Made in France for:

Bayer New Zealand Limited  
3 Argus Place, Hillcrest  
North Shore AUCKLAND 0627

Free phone call: 0800 233 988

This leaflet was last revised on 26 August 2011.

See MEDSAFE website ([www.medsafe.govt.nz](http://www.medsafe.govt.nz)) for latest New Zealand Consumer Medicine Information.

® Registered Trademark of Bayer AG, Germany  
All rights reserved.

