

# Droleptan<sup>®</sup> Injection

## 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 is Droleptan being used?

Droleptan contains the active ingredient droperidol. Droleptan is used in anaesthesia for surgery and some diagnostic procedures. It is also used to help manage severe agitation, aggression and over-activity in some diseases of the brain.

For more information, see Section [1. Why is Droleptan being used?](#) in the full CMI.

### 2. What should I know before Droleptan is used?

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

There are several circumstances in which Droleptan should not be used or when it should only be used with additional caution. **Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant, or are breastfeeding.**

For more information, see Section [2. What should I know before Droleptan is used?](#) in the full CMI.

### 3. What if I am taking other medicines?

**Some medicines must be avoided if Droleptan has been given.** Other medicines may interfere with Droleptan 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 is Droleptan used?

- **Droleptan should be given by a healthcare professional in a medical facility where appropriate monitoring facilities are available.**
- Your doctor will give you Droleptan by injecting it into a muscle or slowly into a vein. Your doctor will monitor your response and may change the dose of Droleptan if you need additional treatment with it.

More instructions can be found in Section [4. How is Droleptan used?](#) in the full CMI.

### 5. What should I know while Droleptan is being used?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>• Tell any other doctors, nurses or other health professionals who treat you that you have been given Droleptan.</li> </ul>
<b>Things to be careful of</b>	<ul style="list-style-type: none"> <li>• If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly will help your body get used to the change in position and blood pressure.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• <b>Be careful before you drive or use any machines or tools until you know how Droleptan affects you.</b> Droleptan may cause dizziness and drowsiness in some people.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• <b>Tell your doctor if you drink alcohol.</b> Be careful drinking alcohol after you have been given this medicine. If you drink alcohol, dizziness or drowsiness may be worse.</li> </ul>

For more information, see Section [5. What should I know while Droleptan is being used?](#) in the full CMI.

### 6. Are there any side effects?

Like all medicines, Droleptan can cause side effects. Not everybody gets side effects but some side effects can be serious.

Drowsiness is reported frequently. Other effects on the nervous system can include dizziness, anxiety, agitation, restlessness, confusion, chills, shivering or seeing, feeling, or hearing things that are not there. Less frequent are tremor, shaky hands, unsteady walk or uncontrolled arm, leg, head, neck or eye movements.

An emergency condition of the nervous system known as neuroleptic malignant syndrome (NMS) can also be caused by Droleptan. Other serious side effects of Droleptan include allergic reaction, breathing distress, blood clots or QT prolongation (an interruption of electrical signalling in the heart).

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.

# Droleptan<sup>®</sup>

Active ingredient: *droperidol*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Droleptan. **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 Droleptan.**

Where to find information in this leaflet:

1. [Why is Droleptan being used?](#)
2. [What should I know before Droleptan is used?](#)
3. [What if I am taking other medicines?](#)
4. [How is Droleptan used?](#)
5. [What should I know while Droleptan is being used?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why is Droleptan being used?

**Droleptan Injection is a tranquilliser used to:**

- calm patients before surgery and some diagnostic procedures
- reduce nausea and vomiting which may occur with anaesthesia
- help produce or maintain anaesthesia
- help reduce anxiety and pain when used with strong pain killers (opioids) in anaesthesia
- help manage severe agitation, aggression and over-activity in brain diseases associated with psychosis or other states of intense, unusual excitement in adults.

**Droleptan contains the active ingredient droperidol.**

There is not enough information to recommend the use of Droleptan for children under the age of 2 years.

**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 Droleptan is used?

### Warnings

**Droleptan should not be used if you have:**

- an allergy to droperidol, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.
- severe drowsiness and slowness as a result of brain disease or damage

- Parkinson's disease
- pheochromocytoma, a type of tumour, which causes high blood pressure
- QT prolongation, sometimes known as long QT syndrome, an electrical signalling disorder of the heart that you can be born with, or that can be caused by other medicines, some medical conditions, or mineral imbalances
- a family history of long QT syndrome.

**Droleptan Injection should not be used if you are intoxicated with alcohol.**

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition

**Tell your doctor if you have or have had:**

- heart disease
- a family history of sudden death
- kidney disease
- lung disease
- dementia, if you are over 65 years of age
- history of blood clots or strokes
- any condition associated with electrolyte disturbances, including persistent vomiting or diarrhoea, alcohol abuse or eating disorders
- epilepsy or convulsions
- sleep apnoea, a sleep disorder where breathing temporarily stops and starts while you sleep.

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

**Tell your doctor if you are pregnant or plan to become pregnant.**

Droleptan should only be used during pregnancy if the benefits outweigh the risks to you and your baby.

Babies exposed to medicines like Droleptan during the third trimester of pregnancy are at risk of experiencing breathing problems, difficulty in feeding, spasms, restlessness, drowsiness, involuntary movements and/or withdrawal symptoms following delivery.

**Ask your doctor to discuss with you the risks and benefits of using Droleptan during pregnancy.**

**Do not breastfeed if you are being given this medicine.**

The active ingredient in Droleptan Injection passes into breast milk and there is a possibility that your baby may be affected.

### 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 must be avoided if Droleptan has been given. These include medicines known to cause QT prolongation, including:**

- some medicines that act on the heart, such as quinidine, disopyramide, procainamide, amiodarone, sotalol and bepridil
- some medicines used to treat depression, such as maprotiline and amitriptyline
- some medicines used to treat mental illness, such as phenothiazines, pimozide and sertindole
- some antihistamines used to treat allergies or hay fever, such as astemizole and terfenadine
- cisapride, a medicine used to treat certain digestive problems
- halofantrine, a medicine used to treat malaria
- sparfloxacin, an antibiotic used to treat lung infections.

**Some medicines may interfere with Droleptan and affect how it works.**

**Your doctor also needs to know if you are taking:**

- medicines that can increase your risk of electrolyte disturbance, such as laxatives, some steroids, some diuretics (water tablets), or insulin in some settings
- alcohol or medicines that make you feel drowsy or slow to react, such as sleeping tablets, tranquillisers or strong pain killers
- medicines used to treat high blood pressure
- medicines used to treat epilepsy, such as phenobarbitone, carbamazepine or phenytoin
- medicines used to treat Parkinson's disease such, as levodopa, bromocriptine, lisuride
- any other medicine. A number of other medicines can affect Droleptan Injection and your doctor can tell you if the medicine you are taking is one of them.

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

### 4. How is Droleptan used?

**Droleptan will be given to you by a healthcare professional in a medical facility where appropriate monitoring facilities are available.**

If necessary, a single dose of Droleptan can be given for the management of acute mania or severe agitation outside the hospital setting provided you are transferred immediately to a hospital setting.

### How much to use

Your doctor will decide how much Droleptan to give you based on many factors including your age, body weight, medical history, other medicines you are receiving and why you are receiving Droleptan.

Your doctor will monitor your response and may change the dose of Droleptan if you need additional treatment with it.

### When Droleptan will be used

When Droleptan is given depends on why it is being used:

- **in anaesthesia**, it can be given before and/or during your surgery or diagnostic procedure
- **in psychiatry**, it is given when you are experiencing severe agitation, aggression and over-activity or other states of intense, unusual excitement. It may be given once or repeated every 4-6 hours if necessary.

### How it is used

Your doctor will give you Droleptan by injecting it into a muscle or slowly into a vein.

### If you use too much Droleptan

As Droleptan Injection is usually given to you in a hospital under the supervision of a doctor, it is unlikely that you will receive an overdose.

**If you think you may have been given an overdose, you should immediately:**

- contact your doctor, or
- phone the Poisons Information Centre **(by calling 13 11 26 in Australia or 0800 764 766 [0800 POISON] in New Zealand)**, or
- go to the Emergency Department at your nearest hospital.

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

**Symptoms of an overdose may include:**

- unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs
- uncontrollable movements
- dizziness, light headedness
- extreme drowsiness
- shallow breathing
- fits
- irregular heartbeat.

### 5. What should I know while Droleptan is being used?

#### Things you should do

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Droleptan Injection.**

Tell any other doctors, nurses or other health professionals who treat you that you have been given Droleptan.

**If you become pregnant after being treated with this medicine, tell your doctor.**

### Things to be careful of

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Droleptan affects you.**

This medicine may cause dizziness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

**Be careful drinking alcohol after you have been given this medicine.**

If you drink alcohol, dizziness or drowsiness may be worse.

### Looking after your medicine

Droleptan will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Droleptan Injection will only be opened when it is time for you to have the injection.

Your doctor or nurse will check to ensure it is a clear, colourless solution, free of particles, and that it is not past its 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.

If you are over 65 years of age, you may be at increased risk of developing some side effects.

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

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

- tremor, shaky hands, an unsteady walk or uncontrolled arm, leg, head, neck or eye movement
- uncontrollable twitching of the tongue, face, mouth or jaw

- muscle spasm causing the head and heels to bend backward and the body to bend forwards
- drowsiness, dizziness, anxiety, agitation, restlessness or confusion
- chills or shivering
- seeing, feeling, or hearing things that are not there
- blurred vision
- yellowing of the skin or eyes, called jaundice
- skin rashes, increased sensitivity to sunlight
- loss of hair
- changes in the menstrual cycle
- breast pain, breast enlargement, unusual secretion of breast milk
- changes in sex drive in men and women
- impotence
- difficulty urinating
- loss of appetite or an uncomfortable feeling in the stomach after eating
- increased saliva or dry mouth
- nausea, vomiting, constipation or diarrhoea.

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

**If any of the following happen, tell your doctor immediately or go to the Emergency Department at your nearest hospital:**

- rash and swelling of the face, lips, mouth, tongue or throat, wheezing or difficulty breathing (may be signs of an allergic reaction)
- any change in your heart rhythm, such as having a fast, pounding, or uneven heartbeat or symptoms such as feeling dizzy or faint (may be signs of QT prolongation)
- severe muscle stiffness, high fever, altered mental state, fast heartbeat, change in blood pressure, increased sweating, rapid, shallow breathing (may be signs of a serious condition called neuroleptic malignant syndrome, NMS)
- slow, shallow breathing, cold or clammy skin, discoloured lips or skin, temporarily stopping breathing (may be signs of respiratory distress)
- sudden severe headache, sudden loss of vision, loss of coordination, slurred speech, chest pain, numbness, heat, or swelling in an arm or a leg (may be signs of a blood clot).

The above list includes very serious side effects which may be life-threatening. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

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 can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://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

Droleptan is a prescription medicine and is only administered under a doctor's supervision.

### What Droleptan contains

<b>Active ingredient (main ingredient)</b>	droperidol
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• tartaric acid</li> <li>• mannitol</li> <li>• water for injections</li> </ul>

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

### What Droleptan looks like

Droleptan Injection is a clear colourless liquid in an amber glass ampoule. It is supplied in packs of 10 ampoules.

Each ampoule contains 2.5 mg droperidol in 1 mL solution for injection (AUST R 46841).

### Who distributes Droleptan

#### Droleptan Injection is supplied in Australia by:

Phebra Pty Ltd  
19 Orion Road, Lane Cove West, NSW 2066, Australia.  
Telephone: 1800 720 020

#### Droleptan Injection is distributed in New Zealand by:

AFT Pharmaceuticals Ltd  
PO Box 33-203, Auckland, New Zealand.  
Telephone: +64 9 4880232

This leaflet was prepared in November 2022.

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