

# DROPERIDOL

## Droperidol solution for 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 am I using Droperidol Medsurge?

Droperidol Medsurge contains the active ingredient droperidol. Droperidol Medsurge is used for the following:

##### **ANAESTHESIA**

Droperidol solution for injection is indicated to produce tranquillisation and to reduce the incidence of nausea and vomiting in surgical and diagnostic procedures; for premedication, induction, and as an adjunct in the maintenance of general and regional anaesthesia; in neuroleptanalgesia in which droperidol solution for injection is given concurrently with a narcotic analgesic, to aid in producing tranquillity and decreasing anxiety and pain.

##### **PSYCHIATRY**

The management of severe agitation, hyperactivity, or aggressiveness in psychotic disorders, including schizophrenic reaction and the manic type of manic depressive illness, or in disturbed states, such as some types of acute brain syndrome and in nonpsychotic acute excitation states

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

#### 2. What should I know before I use Droperidol Medsurge?

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.

**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 Droperidol Medsurge?](#) in the full CMI.

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

Some medicines may interfere with Droperidol Medsurge 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 Droperidol Medsurge?

- Your doctor will decide how much Droperidol solution for injection you will need. This will depend on your age, body weight, medical history and condition.
- Droperidol solution for injection will be injected into a muscle or slowly into a vein.

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

#### 5. What should I know while using Droperidol Medsurge?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using droperidol.</li><li>If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>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</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>If you drink alcohol, dizziness or drowsiness may be worse</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Store below 25°C. Protect from light.</li><li>Product is for single use in one patient only. Discard any residue</li></ul>

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

#### 6. Are there any side effects?

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

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.

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using Droperidol Medsurge. **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 Droperidol Medsurge.**

#### Where to find information in this leaflet:

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

### 1. Why am I using Droperidol Medsurge?

Droperidol Medsurge contains the active ingredient droperidol. Droperidol is a neuroleptic drug of the butyrophenone group that also includes haloperidol.

Droperidol Medsurge is used for the following:

Droperidol Medsurge is only indicated in adults.

#### Anaesthesia

Droperidol Medsurge may be used to produce tranquilisation and to reduce the incidence of nausea and vomiting in surgical and diagnostic procedures. It can also be used for premedication, induction, and as an adjunct in the maintenance of general and regional anaesthesia

In neuroleptanalgesia, droperidol medsurge can be given concurrently with a narcotic analgesic, such as fentanyl injection, to aid in producing tranquillity and in decreasing anxiety and pain.

Provided that certain precautions are taken, droperidol medsurge may be administered as a neuroleptic in all types of surgical interventions.

The indications of choice for neuroleptanalgesia with droperidol medsurge are major and prolonged surgery, interventions involving high risk for the patient or in aged persons, surgery in patients with a poor overall condition, and in individuals who are in shock.

#### Psychiatry

Droperidol Medsurge may be used in the management of severe agitation, hyperactivity, or aggressiveness in psychotic disorders, including schizophrenic reaction and the manic type of manic depressive disorder, or in disturbed states, such

as some types of acute brain syndrome and in non-psychotic acute excitation states.

### 2. What should I know before I use Droperidol Medsurge?

#### Do not use Droperidol Medsurge if:

- you are allergic 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.
- any other similar medicines such as haloperidol.
- you are intoxicated with alcohol

#### Droperidol solution for injection should not be given if you have:

- 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
- a rare heart disorder known as QT prolongation. Sometimes this runs in families
- a slow heart beat
- low levels of salt in your blood.

#### Check with your doctor if you:

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.

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

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

- 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
- vomiting or diarrhoea
- epilepsy or convulsions
- sleep apnoea, temporarily stopping breathing while you sleep.

**You should not be given this medicine if the solution is discoloured, cloudy, turbid, or a precipitate or particles are present. The solution is normally a clear, colourless solution.**

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**Do not use this medicine after the expiry date (EXP) printed on the pack.**

- If you are given it after the expiry date has passed, it may not work very well.

**Do not use this medicine if the packaging is torn or shows signs of tampering or if the injection shows any visible signs of deterioration.**

### 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.

- medicines that act on the heart, such as quinidine, disopyramide, procainamide, amiodarone, sotalol and bepridil
- medicines used to treat depression, such as maprotiline and amitriptyline
- medicines used to treat mental illness, such as phenothiazines, pimozide and sertindole
- medicines used to treat allergies or hay fever, such as astemizole and terfenadine
- 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
- 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 use to treat viral infections, fungal infections or bacterial infections such as ritonavir, itraconazole or ciprofloxacin.

These medicines may be affected by Droperidol solution for injection or may affect how well it works. You may need different amounts of this medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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

Concomitant use of droperidol solution for injection with CYP1A2 inhibitors and/or CYP3A4 inhibitors could decrease the rate of droperidol metabolism and prolong its pharmacological action.

**Medicines that may increase the effect of Droperidol Medsurge include:**

Droperidol may potentiate the action of sedative drugs (barbiturates, benzodiazepines, morphinomimetics). The same applies to antihypertensive agents, so that orthostatic hypotension may ensue.

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

### 4. How do I use Droperidol Medsurge?

#### How much to take / use

Your doctor will decide how much Droperidol solution for injection you will need. This will depend on your age, body weight, medical history and condition.

#### How it is given

Droperidol solution for injection will be injected into a muscle or slowly into a vein.

#### If you use too much Droperidol Medsurge

As Droperidol solution for injection is given to you under the supervision of your doctor; it is very unlikely that you will receive an overdose.

**Symptoms would 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 heart beat

**You should immediately:**

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Droperidol Medsurge.

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

### 5. What should I know while using Droperidol Medsurge?

#### Things you should do

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

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### 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 Droperidol Medsurge 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 when drinking alcohol while you are being given this medicine.

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

### Looking after your medicine

Droperidol solution for injection will be stored in the pharmacy or on the ward.

Store below 25°C. Protect from light.

Product is for single use in one patient only. Discard any residue

#### Keep it where young children cannot reach it.

### 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

### Less Serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• tremor, shaky hands, an unsteady walk or uncontrolled arm, leg, head, neck or eye movement</li><li>• uncontrollable twitching of the tongue, face, mouth or jaw</li><li>• muscle spasm causing the head and heels to bend backward and the body to bend forwards</li><li>• drowsiness, dizziness, anxiety, agitation, restlessness or nervousness</li><li>• chills or shivering</li><li>• seeing, feeling, or hearing things that are not there</li><li>• blurred vision</li><li>• yellowing of the skin or eyes, called jaundice</li><li>• skin rashes, increased sensitivity of the skin to sunlight</li><li>• loss of hair</li><li>• changes in the menstrual cycle</li><li>• breast pain, breast enlargement, unusual secretion of breast milk or changes in sex drive in men and women</li><li>• impotence</li><li>• difficulty urinating</li><li>• loss of appetite or an uncomfortable feeling in the stomach after eating</li><li>• increased saliva, dry mouth</li><li>• nausea, vomiting, constipation or diarrhoea.</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>The list includes serious side effects that may require urgent medical attention. Serious side effects are rare.</b></p>

### Very serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• allergic reaction with rash and swelling of the face, lips, mouth, tongue or throat which may cause difficulty breathing</li><li>• changes in the rhythm or rate of the heart beat</li><li>• difficulty breathing, wheezing and coughing</li><li>• temporarily stopping breathing</li><li>• sudden severe headache</li><li>• loss of vision</li><li>• loss of coordination</li><li>• slurred speech</li><li>• chest pain</li></ul>	<p><b>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.</b></p>

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<ul style="list-style-type: none"><li>• numbness, heat, or swelling in the arms or legs</li><li>• fever, sweating, increased body temperature, stiff muscles, confusion and reduced consciousness.</li></ul>	
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### New Zealand Sponsor

Medsurge Pharma Limited  
PO Box 331054  
Takapuna  
Auckland 0622  
Telephone: 0800 788 261

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

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

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

### Marketed and Distributed by Medsurge Healthcare.

Telephone: 1300 788 261

Website: [www.medsurgehc.com](http://www.medsurgehc.com)

This leaflet was prepared in September 2024.

## 7. Product details

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

### What Droperidol Medsurge contains

<b>Active ingredient (main ingredient)</b>	Droperidol injection contains 1.25 mg/mL or 2.5 mg/mL droperidol.
<b>Other ingredients (inactive ingredients)</b>	Mannitol, tartaric acid, sodium chloride, water for injections
<b>Potential allergens</b>	None

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

### What Droperidol Medsurge looks like

Droperidol Medsurge 1.25 mg/1 mL solution for injection is a sterile, clear colourless solution in 1 mL amber glass ampoule containing 1.25 mg droperidol available in 5 x 1.25 mg/1 mL, 10 x 1.25 mg/1 mL and 50 x 1.25 mg/1 mL packs.

Droperidol Medsurge 2.5 mg/1 mL solution for injection is a sterile, clear colourless solution in 1 mL amber glass ampoule containing 2.5 mg droperidol available in 5 x 2.5 mg/1 mL, 10 x 2.5 mg/1 mL and 50 x 2.5 mg/1 mL packs.

Not all presentations or pack sizes are marketed.  
Droperidol Medsurge 1.25 mg/1 mL: AUST R 353873  
Droperidol Medsurge 2.5 mg/1 mL: AUST R 353872

### Who distributes Droperidol Medsurge

Medsurge Pharma Pty Ltd  
Unit 1&2, 6-7 Gilda Court  
Mulgrave, Victoria 3170