Package leaflet: Information for the user
Droperidol 0.5 mg/ml Solution for Injection
droperidol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Droperidol is and what it is used for
2. What you need to know before you are given Droperidol
3. How you will be given Droperidol
4. Possible side effects
5. How to store Droperidol
6. Contents of the pack and other information

1. What Droperidol is and what it is used for

Droperidol is a solution for injection containing the active substance droperidol, which is used:

- to prevent you feeling sick (nausea) or vomiting
- when you wake up after an operation (primarily used in adults and, as a second line, in children [2 to 11 years] and adolescents [12 to 18 years]) or
- in adults when you receive morphine-based painkillers after an operation.

2. What you need to know before you are given Droperidol

You must not be given Droperidol if you:

- are allergic (hypersensitive) to droperidol, or any of the other ingredients of this medicine (listed in section 6)
- are allergic to a group of medicines used to treat psychiatric disorders, called butyrophenones, e.g. haloperidol, triperidol, benperidol, melperone, domperidone
- or anyone in your family have an abnormal electrocardiogram (ECG) heart tracing
- are taking any medicine that can affect the ECG (see section Other medicines and Droperidol)
- have low levels of potassium or magnesium in your blood
- have a pulse rate of less than 55 beats per minute (the doctor or nurse will check this), or are taking any medicines that could cause this to happen
- have a tumour in your adrenal gland (phaeochromocytoma)
- are in a coma
- have Parkinson's disease
- have severe depression.

Warnings and precautions

Before you are given Droperidol, you should tell your doctor or nurse if you:

- have epilepsy, a history of epilepsy
- have any heart problems or if you have any history of heart problems

- have a family history of sudden death
- have kidney problems especially if you are on long-term dialysis
- have lung disease and any breathing difficulties
- have prolonged sickness or diarrhoea
- are taking insulin
- are taking potassium-wasting diuretics i.e. water tablets (e.g. furosemide or bendroflumethiazide)
- are taking laxatives
- are taking glucocorticoids (a type of steroid hormone)
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- are or have been a heavy drinker (of alcohol).

Other medicines and Droperidol
Tell your doctor or nurse if you are taking or have recently taken **any** other medicines including those you have obtained without a prescription. This is because droperidol can affect the way some other medicines work. Also, some medicines can affect the way droperidol works.

You should not be given Droperidol if you are taking any of the following medicines. These medicines increase the chance of you getting side effects, some of which can be severe, if mixed with droperidol

What the medicine is used for	Medicine(s
Heart conditions	Quinidine, disopyramide, procainamide, amiodarone or sotalol
Antibiotics	Azithromycin, erythromycin, clarithromycin, sparfloxacin
Allergies	Astemizole, terfenadine
Depression	Amitriptyline, maprotiline, fluoxetine, sertraline, fluvoxamine
Mental illnesses e.g. schizophrenia	Amisulpride, chlorpromazine, haloperidol, melperone, phenothiazines, pimozide, sulpiride, sertindole, tiapride
Malaria	Quinine, chloroquine, halofantrine
Heartburn	Cisapride
Infection	Pentamidine
Control of the immune system	Tacrolimus
Breast cancer	Tamoxifen
Increases blood flow to the brain	Vincamine
Nausea (feeling sick) or vomiting	Metoclopramide, Domperidone
Opioid dependence; pain	Methadone

Metoclopramide and other neuroleptics should be avoided when taking Droperidol, since the risk of movement disorders induced by these medicines is increased.

Droperidol, the active ingredient in Droperidol 0.5 mg/ml Solution for Injection, can increase the effects of sedatives such as barbiturates, benzodiazepines and morphine-based products. It can also

increase the effects of medication used to lower high blood pressure (antihypertensives) and a number of other medicines e.g. certain antifungals, antivirals, and antibiotics.

Some medicines may also increase the effects of droperidol e.g. cimetidine (for gastric ulcers), ticlopidine (to prevent blood-clotting) and mibefradil (for angina).

If you are in any doubt, please talk to your doctor or nurse.

Droperidol with alcohol

Avoid drinking any alcohol for 24 hours before and after being given Droperidol.

Pregnancy and breast-feeding

If you are **pregnant**, inform your doctor who will decide if you should receive Droperidol.

If you are **breast-feeding** and will be given Droperidol then it is recommended that you receive only one administration of Droperidol. Breast-feeding can be resumed on waking after your operation.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Droperidol has a major effect on the ability to drive and use machines.
Do not drive or use machinery for at least 24 hours after taking Droperidol.

Droperidol contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per 1ml, i.e. essentially 'sodium-free'.

3. How you will be given Droperidol

Droperidol will be given to you by your doctor by an injection into a vein.

The amount of Droperidol and the way in which it is given will depend on the situation. Your doctor will determine how much Droperidol you need based on a number of things including your weight, age and medical condition.

The usual adult dosage is 0.625 to 1.25 mg, reduced to 0.625 mg for the elderly (over 65 years) and those with renal and kidney impairment.

The dosage in children (2 to 11 years) and adolescents (12 to 18 years) is based on their body weight (10 to 50 microgram/kg) but up to a maximum of 1.25 mg. Droperidol is not recommended in children below 2 years.

If you have any further questions on the use of this product, please ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of these side effects may be serious.

Tell your doctor or nurse immediately if you experience any of the following serious side effects:

- increase in your body temperature (fever), muscle stiffness, tremor, change in blood pressure, excessive sweating or increase salivation. This may be a sign that you have neuroleptic malignant syndrome (NMS), a **rare** side effect of this medicine.

- serious allergic reaction or rapid swelling of the face or throat (angioedema), a **rare** side effect.
- heart attack (cardiac arrest), a **very rare** side effect.
- **blood clots** in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing (frequency is not known). If you notice any of these symptoms seek medicinal advice immediately.

The following side effects have also been reported:

Common (may affect up to 1 in 10 people)
- Feeling drowsy or sleepy
- Low blood pressure

Uncommon (may affect up to 1 in 100 people)
- Feeling anxious
- Feeling restless and unable to stay still with a need to move
- Feeling dizzy
- Rolling of the eyes
- Fast heartbeat e.g. more than 100 beats per minute

Rare (may affect up to 1 in 1,000 people)
- Serious allergic reaction known as anaphylaxis or anaphylactic shock
- Feeling confused
- Feeling agitated
- Abnormal or irregular heartbeat
- Rash

Very rare (may affect up to 1 in 10,000 people)
- Blood disorders (usually diseases affecting red blood cells or platelets). Your doctor can advise you.
- Change in mood towards sadness, anxiety, depression and irritability
- Involuntary muscle movements
- Convulsions or tremors
- Torsade de pointes (life-threatening irregular heartbeat)
- Prolonged QT interval in ECG (a heart condition affecting the heartbeat)
- Sudden death

Not known (frequency cannot be estimated from the available data):
- Inappropriate anti-diuretic hormone secretion (too much of the hormone is released leading to excess water and low sodium levels in the body)
- Hallucinations
- Epileptic seizures
- Parkinson's disease
- Psychomotor hyperactivity
- Coma
- Fainting
- Breathing difficulties

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA

Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Droperidol

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the ampoule after EXP. The expiry date refers to the last day of that month.

The solution should be used immediately on first opening.

Your doctor will check that the solution is clear and contains no particles before using it.

The person who gave you this medicine will be responsible for disposing it. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Droperidol contains

- The active substance is droperidol, each millilitre of solution contains 0.5 mg droperidol.
- The other ingredients are s-lactic acid (also for pH adjustment) and water for injections.

What Droperidol looks like and contents of the pack

Droperidol 0.5 mg/ml solution for injection is a clear, colourless solution for injection.
The solution is contained in amber glass ampoules. Each ampoule contains 2.5 millilitres of solution and ampoules are packaged in cartons containing 10 ampoules.

Marketing Authorisation Holder and Manufacturer

Sintetica GmbH
Albersloher Weg 11
48155 Münster
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland	Droperidol
Denmark Finland Iceland Norway Sweden	Droperidol Sintetica
Italy	Droperidolo Sintetica
Romania	Droperidol Sintetica 0.5 mg/ml solutie injectabila

This leaflet was last revised in June 2023

Package Leaflet: Information for Healthcare Professional
Droperidol 0.5 mg/ml, solution for injection

The following information is intended for healthcare professionals only:

Qualitative and quantitative composition
Each millilitre of solution contains 0.5 mg droperidol.
One ampoule 2.5 ml contains 1.25 mg droperidol

Therapeutic indications
Prevention and treatment of post-operative nausea and vomiting (PONV) in adults and, as second line, in children (2 to 11 years) and adolescents (12 to 18 years).
Prevention of nausea and vomiting induced by morphine and derivatives during post-operative patient-controlled analgesia (PCA) in adults.

Posology and method of administration
For intravenous use. Administer slowly (hypotonic solution).

Prevention and treatment of post-operative nausea and vomiting (PONV).

Posology:

Adults: 0.625 mg to 1.25 mg (1.25 to 2.5 ml).

Elderly (over 65 years): 0.625 mg (1.25 ml)

Renal/hepatic impairment: 0.625 mg (1.25 ml)

Paediatric population

Children (2 to 11 years) and adolescents (12 to 18 years): 10 to 50 microgram/kg (up to a maximum of 1.25 mg).
Children (below the age of 2 years): not recommended.

For prevention of PONV, antiemetics are indicated in patients at moderate and high risk. The risk should be assessed using standard accepted scales or scores, such as the Modified APFEL Score.

Administration of Droperidol is recommended 30 minutes before the anticipated end of surgery. Repeat doses may be given every 6 hours as required.

In adults, prevention of early vomiting and late nausea may be improved by doses above 0.75 mg, but not greater than 1.25 mg.

In adults and children, higher doses are associated with increased risk of sedation and drowsiness.

Prevention of nausea and vomiting induced by morphine and derivatives during post-operative patient-controlled analgesia (PCA).

Posology:

Adults: 15 to 50 micrograms droperidol per mg of morphine, up to a maximum daily dose of 5 mg droperidol.

Elderly (over 65 years), renal and hepatic impairment: no data in PCA available.

Paediatric population

Children (2 to 11 years) and adolescents (12 to 18 years): not indicated in PCA.

In patients with identified or suspected risk of ventricular arrhythmia continuous pulse oximetry and continuous ECG and should continue for 30 minutes following single i.v. administration.

For instructions on dilution of the medicinal product before administration, see Handling instructions.

Pharmacokinetic properties

The action of a single intravenous dose commences 2-3 minutes following administration. The tranquillising and sedative effects tend to persist for 2 to 4 hours, although alertness may be affected for up to 12 hours.

Distribution

Following intravenous administration, plasma concentrations fall rapidly during the first 15 minutes; this is metabolism independent, redistribution of the drug. Plasma protein binding amounts to 85 – 90 %. The distribution volume is approximately 1.5 l/kg.

Metabolism

Droperidol is extensively metabolised in the liver, and undergoes oxidation, dealkylation, demethylation and hydroxylation by cytochrome P450 isoenzymes 1A2 and 3A4, and to a lesser extent by 2C 19. The metabolites are devoid of neuroleptic activity.

Elimination

Elimination occurs mainly through metabolism; 75% is excreted via the kidneys. Only 1% of the active substance is excreted unchanged with urine, and 11% with faeces. Plasma clearance is 0.8 (0.4 - 1.8) l/min. The elimination half-life (t1/2ß) is 134 ± 13 min.

Drug Interactions

A study combining ondansetron (4 mg) and droperidol (1 mg) showed that when administered together there was no pharmacokinetic interaction between the two drugs.

Paediatric Population

In a study of 12 children (age 3.5 to 12 years), the values for distribution volume and clearance reported were lower than those found in the adult population (0.58 ± 0.29 l/kg and 4.66 ± 2.28 ml/kg*min respectively) and decrease in parallel. The elimination half-life (101.5 ± 26.4 min) was similar to that found in adults.

Incompatibilities

Incompatible with barbiturates. This medicinal product must not be mixed with other medicinal products except morphine for use in PCA.

Handling instructions

The solution should be used immediately on first opening.

After dilution: Chemical and physical in-use stability of 5 mg droperidol with 100 mg morphine sulphate in 50 ml of 0.9% sodium chloride has been demonstrated in plastic syringes up to 14 days at 25°C and at 2 to 8°C.

From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Storage and Shelf life

For single use only. Any unused solution should be discarded.

Do not use this medicine if you notice signs of deterioration. The product should be visually inspected prior to use and only clear solutions practically free from particles should be used.

For full prescribing information please refer to the Summary of Product Characteristics.