Package leaflet: Information for the user

Droperidol 1.25 mg/ml solution for injection
Droperidol 2.5 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.
- 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

Droperidol contains the active substance droperidol, which belongs to a group of antipsychotics called butyrophenone derivatives. It is used to prevent you feeling sick (nausea) or vomiting when you wake up after an operation or 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 to droperidol or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to a group of medicines used to treat psychiatric disorders, known as butyrophenones (such as, haloperidol, triperidol, benperidol, melperone, domperidone);
- if you or anyone in your family have an abnormal electrocardiogram (ECG) heart tracing;
- if you have low levels of potassium or magnesium in your blood;
- if you 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;
- if you have a tumour in your adrenal gland (phaeochromocytoma);
- if you are in a coma;
- if you have Parkinson's disease;
- if you have severe depression.

Warnings and precautions
Talk to your doctor or nurse before you are given Droperidol :
- if you have epilepsy, or a history of epilepsy;
- if you have any heart problems or if you have any history of heart problems;
- if you have a family history of sudden death;
- if you have kidney problems (especially if you are on long-term dialysis);

- if you have lung disease and any breathing difficulties;
- if you have prolonged nausea or diarrhoea;
- if you are using insulin;
- if you are taking potassium-wasting diuretics such as. water tablets (for example. furosemide or bendroflumethiazide);
- if you are taking laxatives;
- if you are taking glucocorticoids (a type of steroid hormone);
- if you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots;
- if you are or have been a heavy drinker (of alcohol).

Other medicines and Droperidol
Tell your doctor if you are using, have recently used or might use,any other medicines.

You should not be given Droperidol if you are taking any of the following medicines.

What the medicine is used for	**Medicine(s)**
Heart arrhythmia, irregular heart beats	Class IA and III antiarrhythmics
Infection (bacterial)	Antibiotics of the macrolide and fluoroquinolone type
Malaria	Anti-malaria medicines
Allergies	Antihistamines
Mental illnesses e.g. schizophrenia	Antipsychotics
Heartburn	Cisapride
Parasite infestation or fungal infection	Pentamidine
Nausea (feeling sick) or vomiting	Domperidone
Opioid dependence; pain	Methadone

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

Other medicines that may affect or be affected when used at the same time as Droperidol.
droperidol,:
- can increase the effects of sedatives such as barbiturates, benzodiazepines and morphine based medicines;
- can increase the effects of medicines used to lower high blood pressure;
- can increase the effects of a number of other medicines such as certain antifungals, antivirals, and antibiotics.

Talk to your doctor or nurse if you are taking any of these medicines.

Droperidol with alcohol
Consumption of alcoholic beverages and medicinal products should be avoided

Pregnancy and breast-feeding
If you are pregnant, inform your doctor who will decide if you should receive Droperidol.
The following symptoms may occur in newborn babies, of mothers that have used this medicine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms contact your doctor.

If you are breast-feeding and are going to be given Droperidol, the treatment will be limited to only one administration. Breast-feeding can be resumed on waking after your operation.

Driving and using machines
Droperidol has a major effect on the ability to drive and use machines.
Do not drive or use machines for at least 24 hours after being given this medicine.

Droperidol contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium free'.

3. How Droperidol is given

Droperidol will be given to you by your doctor.

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.

Droperidol will be given by an injection into a vein (intravenous use).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor or nurse immediately if you experience any of the following serious side effects:
- increase in your body temperature, sweating, salivation, muscle stiffness, tremor. These may be signs of so called neuroleptic malignant syndrome (rare side effect).
- serious allergic reaction or rapid swelling of the face or throat; difficulty swallowing; hives and difficulty breathing (rare side effect)

The following side effects have also been reported:

<u>Common: may affect up to 1 in 10 people</u>
- drowsiness.
- low blood pressure.

<u>Uncommon: may affect up to 1 in 100 people</u>
- anxiety.
- rolling of the eyes.
- fast heartbeat e.g. more than 100 beats per minute.
- dizziness.

<u>Rare: may affect up to 1 in 1,000 people</u>
- confusion.
- agitation.
- irregular heartbeat.
- rash.

Very rare: may affect up to 1 in 10,000 people
- blood disorders (usually 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.
- heart attack (cardiac arrest).
- sudden death.
- torsade de pointes (life-threatening irregular heartbeat).
- prolonged QT interval in ECG (a heart condition affecting the heartbeat).

Unknown 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.
- fainting.
- breathing difficulties.

Reporting of side effects

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

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.

Store in the original package in order to protect from light.
After dilution
Chemical and physical in-use stability of droperidol has been demonstrated:
- with glucose 50 mg/mL (5%) solution in PVC infusion bags and PVC-free infusion bags and polypropylene syringes for 48 hours at 25°C.
- with sodium chloride 9 mg/mL (0.9%) solution for injection in PVC infusion bags and PVC-free infusion bags and polypropylene syringes for 48 hours at 25°C.
- with morphine in sodium chloride 9 mg/mL (0.9%) solution for injection in polypropylene syringes for 14 days at 25°C and at 2 to 8°C.

From a microbiological point of view, the diluted medicinal 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.

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

Droperidol 1.25 mg/ml solution for injection
Each 1 ml ampoule contains 1.25 mg droperidol.

Droperidol 2.5 mg/ml solution for injection
Each 1 ml ampoule contains 2.5 mg droperidol.

The other ingredients are mannitol (E 421), tartaric acid, sodium hydroxide (for pH adjustment), water for injections.

What Droperidol looks like and contents of the pack

This medicine is a clear, colourless solution for injection (injection).
The solution is contained in amber coloured glass ampoules.
Box of 10 ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Laboratoire Aguettant
1 rue Alexander Fleming
Lyon, 69007
France

Manufacturer:
Laboratoire Aguettant
1, rue Alexander Fleming
Lyon, 69007
France

This medicinal product is authorised in the Member States of the EEA under the following names:
AT, BE, DE, DK, ES, FI, IS, LU, NL, NO, PT, RO, SE: Droperidol Aguettant
IE: Droperidol
IT: Droperidolo Aguettant

This leaflet was last revised in 10/2024.
Detailed information on this medicine is available on the HPRA website.