PACKAGE LEAFLET: INFORMATION FOR THE USER

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 or pharmacist.
- 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 or pharmacist. 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 is a solution of droperidol for injection, which is used in adults, children (2 to 11 years) and adolescents (12 to 18 years) to prevent you feeling sick (nausea) or vomiting when you wake up after an operation or in adults for preventing feeling sick (nausea) or vomiting when you receive morphine based painkillers after an operation.

The active substance in Droperidol is droperidol. Droperidol belongs to a group of antipsychotics called butyrophenone derivatives.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DROPERIDOL

Do not use 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, called butyrophenones (e.g. 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 pharmacist before using Droperidol, especially if you:
- have epilepsy, or 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)
- 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
- are or have been a heavy drinker (of alcohol)

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

Do not use Droperidol if you are taking any of the following medicines:

What the medicine is used for	Medicine(s)
Heart conditions	Quinidine, disopyramide, procainamide, amiodarone or sotalol
Antibiotics	Erythromycin, clarithromycin, sparfloxacin
Allergies	Astemizole, terfenadine
Mental illnesses e.g. schizophrenia etc.	Chlorpromazine, haloperidol, pimozide, thioridazine
Malaria	Chloroquine, halofantrin
Heartburn	Cisapride
Infection	Pentamidine
Nausea (feeling sick) or vomiting	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, 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 food and alcohol
Avoid drinking any alcohol for 24 hours before and after being given Droperidol.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

The following information is intended for healthcare professionals only

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Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities
Incompatible with barbiturates.

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

3. HOW TO USE 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 hepatic 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.

Contact your doctor immediately if you experience any increase in your body temperature, muscle stiffness, tremor, rapid swelling of the face or throat, or if you get chest pains after having this medicine.

The following side effects have also been reported: If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

Common side effects (may affect up to 1 in 10 people)
- Drowsiness
- Low blood pressure

Uncommon side effects (may affect up to 1 in 100 people)
- Anxiety
- Rolling of the eyes
- Fast heartbeat e.g. more than 100 beats per minute
- Dizziness

Rare side effects (may affect up to 1 in 1,000 people)
- Serious allergic reaction known as anaphylaxis or anaphylactic shock
- Confusion
- Agitation
- Irregular heartbeat
- Rash
- Neuroleptic malignant syndrome, symptoms include fever, sweating, salivation, muscle stiffness and tremors

Very rare side effects (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
- Heart attack (cardiac arrest)
- Torsade de pointes (life-threatening irregular heartbeat)
- Prolonged QT interval in ECG (a heart condition affecting the heartbeat)
- Sudden death

Other side effects which may occur are:
- 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
- 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. If you notice any of these symptoms seek medical advice immediately.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. 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 vial after EXP. The expiry date refers to the last day of that month.

Store in the original package.

The solution should be used immediately after first opening.

Compatibility of droperidol with morphine sulphate in 0.9% sodium chloride (14 days at room temperature) has been demonstrated in plastic syringes. 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.

Do not use droperidol 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.

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 is droperidol, each millilitre of solution contains 2.5 mg droperidol.
- The other ingredients are DL-lactic acid and water for injections.

What Droperidol looks like and contents of the pack
The solution is a clear colourless solution which is contained in 2 ml amber glass vials (type I). Each vial contains 1 millilitre of solution in packs of 10 and 25 vials.

Not all pack sizes may be marketed.

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Instructions for use and handling, and disposal
For single use only. Any unused solution should be discarded.

The solution should be inspected visually prior to use. Only clear and colourless solutions free from visible particles should be used.

For use in PCA: Draw droperidol and morphine into a syringe and make up the volume with 0.9% sodium chloride for injection.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.