



DROPERIDOL PANPHARMA 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 nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

What is in this leaflet

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2. What you need to know before you are given DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection
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1. What DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection is and what it is used for

DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection is a solution of droperidol for injection, which 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.

Droperidol belongs to a group of antipsychotics called butyrophenone derivatives.

2. What you need to know before you are given DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection

You should not be given DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection if you:

- are allergic (hypersensitive) to the active ingredient droperidol, or any of the other ingredients in DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection (a list of these can be found in Section 6 of this leaflet.)
- 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
- 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 PANPHARMA 2.5 mg/ml, solution for injection, you should tell your doctor or nurse 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 PANPHARMA 2.5 mg/ml, solution for injection

Always tell your doctor or nurse if you are taking or have recently taken **any** other medicines including those you have obtained without a prescription, as a number of medicines cannot be mixed with droperidol.

Do not take DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection 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, melperone, phenothiazines, pimozide, thioridazine
Malaria	Chloroquine, halofantrine
Heartburn	Cisapride
Infection	Pentamidine
Nausea (feeling sick) or vomiting	Domperidone
Opioid dependence; pain	Methadone

Metoclopramide and other neuroleptics should be avoided when taking DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection since the risk of movement disorders induced by these medicines is increased.

Droperidol, the active ingredient in DROPERIDOL PANPHARMA 2.5 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 PANPHARMA 2.5 mg/ml, solution for injection with food and drink

Avoid drinking any alcohol for 24 hours before and after being given DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection.

Pregnancy and breast-feeding

If you are pregnant, inform your doctor who will decide if you should receive DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection.

If you are breast-feeding and are going to take DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection then it is recommended that you receive only one administration of DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection. 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 PANPHARMA 2.5 mg/ml, solution for injection.

DROPERIDOL contains sodium

DROPERIDOL contains less than 1 mmol sodium (23mg) per 1 ml, i.e. essentially "sodium-free".

3. How you will be given DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection

DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection will be given to you by your doctor by an injection into a vein.

The amount of DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection and the way in which it is given will depend on the situation. Your doctor will determine how much DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection 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 PANPHARMA 2.5 mg/ml, solution for injection is not recommended in children below 2 years.

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

Instructions for use

Opening the ampoule

1. Hold the ampoule between your thumb and index finger with the top of the ampoule showing.
2. With the other hand, grasp the upper part of the ampoule, with your index finger placed against the neck, and your thumb on the coloured point parallel to the coloured rings (or ring).
3. Keeping your thumb on the point, break the top of the ampoule with a sharp movement firmly holding the body of the ampoule in your hand. 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:

Common side effects (likely to affect less than 1 in 10 people and more than 1 in 100)

- Drowsiness
- Low blood pressure

Uncommon side effects (likely to affect less than 1 in 100 people and more than 1 in 1,000)

- Anxiety
- Rolling of the eyes
- Fast heartbeat e.g. more than 100 beats per minute
- Dizziness

Rare side effects (likely to affect less than 1 in 1,000 people and more than 1 in 10,000)

- 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 (likely to affect less than 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 PANPHARMA 2.5 mg/ml, solution for injection

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.

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 for 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.

Do not use DROPERIDOL PANPHARMA 2.5 mg/ml, Solution for Injection 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 PANPHARMA 2.5 mg/ml, solution for injection contains

- The active substance is droperidol, each millilitre of solution contains 2.5 mg droperidol.
- The other ingredients are mannitol (E421), tartaric acid (E334), sodium hydroxide (for pH adjustment), water for injections.

What DROPERIDOL PANPHARMA 2.5 mg/ml, solution for injection looks like and contents of the pack

DROPERIDOL PANPHARMA 2.5 mg/ml, Solution for Injection is a clear, colourless solution for injection.

The solution is contained in amber coloured glass ampoules. Each ampoule contains 1 millilitre of solution and packaged in cartons containing either 10 ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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BUNSENSTRASSE 4
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This medicinal product is authorised in the Member States of the EEA under the following names:

France	DROPERIDOL PANPHARMA 2,5 mg/ml, solution injectable
Germany	Droperidol PANPHARMA 2,5 mg/ml Injektionslösung
Portugal	Droperidol Panpharma 2,5 mg/ml, solução injectável
United Kingdom	Droperidol Panpharma 2.5 mg/ml Solution for Injection

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