PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

Droperidol Equity 1,25 mg/mL solution for injection

Droperidol

Contains sugar (mannitol 47,0 mg per mL)

Read all of this leaflet carefully before you are given Droperidol Equity

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What Droperidol Equity is and what it is used for

Droperidol Equity is a solution for injection containing the active substance droperidol, which belongs to a group of medicines called butyrophenone derivatives.

Droperidol Equity it is a medicine used to prevent you from 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 use Droperidol Equity

Droperidol Equity should not be administered to you if:

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- you are allergic (hypersensitive) to droperidol or to any of the other ingredients in Droperidol Equity (listed in section 6);
- you are allergic to a group of medicines used to treat psychiatric disorders, called butyrophenones (e.g. haloperidol, triperidol, benperidol, melperone, domperidone);
- you or anyone in your family have an abnormal electrocardiogram (ECG) heart tracing;
- you are taking medicines that is known to induce a condition called torsades de pointes (specific type of abnormal heart rhythm). These medicines include amiodarone, amisulpride, disopyramide, dronedarone, hydroquinidine, quinidine, sotalol), citalopram, escitalopram, cocaine, domperidone, erythromycin administered by intravenous route, hydroxyzine, mequitazine, moxifloxacin, piperaquine, spiramycin, toremifene, vincamine, vandetanib;
- you have low levels of potassium or magnesium in your blood;
- 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;
- you have a tumour in your adrenal gland (pheochromocytoma);
- you have Parkinson's disease;
- you have severe depression;
- you are taking dopaminergic medicine (medicine that works by acting on certain types of cells in your brain). These medicines include amantadine, apomorphine, bromocriptine, cabergoline, entacapone, lisuride, piribedil, pramipexole, quinagolide, rasagiline, ropinirole, rotigotine, selegiline, tolcapone).

Patients that are in a coma, should not receive Droperidol Equity.

Warnings and precautions

Special care should be taken with Droperidol Equity:

- if you are on any medicine that supresses your nervous system (e.g., diazepam, alprazolam and certain sleep medicine)
- if you are taking metoclopramide (anti-sickness medicine) and other antipsychotic or tranquilising medicine

(e.g., pimozide, thiothixene, risperidone, promazine)

- 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 persistent nausea or diarrhoea or any other electrolyte disturbance;
- if you use insulin;
- if you are taking potassium-wasting diuretics i.e. water tablets (e.g. 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, such medicines have been associated with formation of blood clots;
- if you are or have been a heavy drinker (of alcohol);
- if you are taking medicine that may affect your heart rhythm, such as arsenic trioxide, antiparasitic medicines likely to induce torsades de pointes (chloroquine, halofantrine, lumefantrine, pentamidine), neuroleptics likely to induce torsades de pointes (chlorpromazine, cyamemazine, flupentixol, fluphenazine, haloperidol, levomepromazine, pimozide, pipamperone, pipotiazine, sulpiride, tiapride, zuclopenthixol), delamanid, crizotinib, hydroxychloroquine, methadone, sulfamethoxazole + trimethoprim.

Mild to moderate low blood pressure and occasionally rapid heart rate, has been observed following the administration of Droperidol Equity. This reaction usually subsides spontaneously. However, should the low blood pressure persist, you should contact your doctor as fluid replacement should be considered.

In case of unexplained high body temperature, it is essential to discontinue treatment, since this sign may be one of the elements of malignant syndrome. The symptoms of this syndrome are very high fever, irregular pulse, accelerated heartbeat (tachycardia), increased rate of respiration, muscle rigidity, altered mental status,

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autonomic nervous system dysfunction resulting in high or low blood pressure, profuse perspiration, and excessive sweating.

If you are elderly, or have impaired kidney or liver function, your dose will have to be reduced.

Children

Droperidol Equity is not indicated in children under 2 years of age.

Other medicines and Droperidol Equity

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Medicines that may affect, or be affected by Droperidol Equity are:

- medicines used to treat heart conditions (quinidine, hydroquinidine, disopyramide, procainamide, amiodarone, sotalol or other beta blockers, dronedarone);
- medicines used as antibiotics (erythromycin, clarithromycin, sparfloxacin, spiramycin, moxifloxacin, sulfamethoxazole + trimethoprim, azithromycin, roxithromycin, ciprofloxacin, levofloxacin, norfloxacin);
- medicines used to treat allergies (astemizole, terfenadine, mequitazine);
- medicines used to treat mental illnesses e.g., schizophrenia etc. (chlorpromazine, haloperidol, phenothiazines, pimozide, thioridazine, risperidone, sertindole, cyamemazine, flupentixol, fluphenazine, levomepromazine, pipamperone, pipotiazine, sulpiride, tiapride, zuclopenthixol, lithium);
- medicines used to treat malaria (chloroquine, halofantrine, piperaquine, hydroxychloroquine);
- medicine used to treat heartburn (cisapride);
- medicine used to treat infection (pentamidine);
- medicine used to treat nausea (feeling sick) or vomiting (domperidone, ondansetron);
- medicine used to treat opioid dependence; pain (methadone).
- medicine used for treatment of Parkinson's disease (amantadine, apomorphine, bromocriptine, cabergoline, entacapone, lisuride, piribedil, pramipexole, quinagolide, rasagiline, ropinirole, rotigotine, selegiline,

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tolcapone, levodopa

- medicines used in cancer treatment (toremifene, vandetanib, crizotinib, glasdegib)
- anti-depressant medicines (amitriptyline, citalopram, escitalopram, maprotiline)
- anti-parasitic medicine e.g., lumefantrine, pentamidine
- tuberculosis treatment called delamanid
- sodium oxybate used in the treatment of narcolepsy (a chronic sleep disorder that causes overwhelming daytime drowsiness
- anagrelide used to decrease the risk of blood clots

The combination of metoclopramide (medicine to treat nausea) and other antipsychotic or tranquilising medicine (e.g., pimozide, thiothixene, risperidone, promazine) with Droperidol Equity should be avoided due to the increased risk of motor disorders induced by these medicines.

Droperidol, as contained in Droperidol Equity, can increase the effects of sedatives such as barbiturates, benzodiazepines and morphine-based medicines. It can also increase the effects of medicine used to lower high blood pressure (antihypertensives) and a number of other medicines e.g., certain antifungals, antivirals, and antibiotics. Some medicines e.g., cimetidine (for gastric ulcers), ticlopidine (to prevent blood-clotting) and mibefradil (for angina) may increase the effects of Droperidol Equity. If you are not sure please talk to your doctor or pharmacist.

Droperidol Equity with food and drink

Consumption of alcoholic beverages and medicines containing alcohol should be avoided. If you have, or are suspected of having, a history of alcohol abuse or recent high intakes, your risk of heart side effects are increased.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

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As a precaution, it is best not to administer Droperidol Equity during pregnancy.

Droperidol Equity is excreted in breast milk. You should not breastfeed your infant while receiving Droperidol Equity.

Driving and using machines

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

3. How to use Droperidol Equity

Do not share medicines prescribed for you with any other person.

Droperidol Equity should only be administered to you in a hospital by specialised healthcare professionals.

You will not be expected to give yourself Droperidol Equity. It will be given to you by a person who is qualified to do so.

Your doctor will give you Droperidol Equity intravenously (into a vein).

The amount of Droperidol Equity and the manner in which it will be administered depend on your age, body weight, use of other medicines and surgical procedure involved. Your doctor will determine the dose of Droperidol Equity required in your case.

If you receive more Droperidol Equity than you should

Since a healthcare provider will administer Droperidol Equity, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use a dose of Droperidol Equity

Since a healthcare provider will administer Droperidol Equity, it is unlikely that the dose will be missed.

4. Possible side effects

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Droperidol Equity can have side effects.

Not all side effects reported for Droperidol Equity are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Droperidol Equity, please consult your healthcare provider for advice.

If any of the following happens, stop receiving Droperidol Equity and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- increase in your body temperature, sweating, salivation, muscle stiffness, tremor. These may be signs of so called neuroleptic malignant syndrome.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Droperidol Equity. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- drowsiness
- low blood pressure

Less frequent side effects

- blood disorders (usually involving red blood cells or platelets). Your doctor will advise you.
- anxiety
- a feeling of muscle quivering, restlessness and inability to sit still
- confusion

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- agitation
- a state of feeling uneasy, unhappy or unwell.
- involuntary muscle movements
- rolling of the eyes
- convulsions or tremors
- fast heartbeat e.g. more than 100 beats per minute
- dizziness
- irregular heart beat
- heart attack (cardiac arrest)
- torsade de pointes (life-threatening irregular heartbeat)
- prolonged QT interval in ECG (a heart condition affecting the heartbeat)
- rash
- sudden death

Frequency unknown

- 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
- coma
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Droperidol Equity.

5. How to store Droperidol Equity

- Store all medicines out of reach of children.
- Store at or below 25 ºC.
- Protect from light.
- Store the ampoules in the original package until required for use.
- The solution should be used immediately after first opening.
- For single use only. Any unused solution should be discarded.
- Do not use Droperidol Equity if you notice signs of deterioration. The injection should be visually inspected prior to use and only clear solutions practically free from particles should be used.
- Do not store in a bathroom.
- Do not use the injection after the expiry date printed on the label/ blister pack.
- Return all unused medicine to your pharmacist.
- 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 Equity contains

The active substance is droperidol.

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

What Droperidol Equity looks like and contents of the pack

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Droperidol Equity is a clear, sterile solution, free from any visible particles.

Droperidol Equity is packaged in 1 ml one point cut ampoules made of brown type I glass.

The ampoules are packaged in thermoformed blisters strips or in paper racks placed inside cardboard boxes, 10 ampoules per box.

Holder of Certificate of Registration

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