PACKAGE LEAFLET: INFORMATION FOR THE USER

Xomolix 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 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 Xomolix is and what it is used for
2. What you need to know before you use Xomolix
3. How to use Xomolix
4. Possible side effects
5. How to store Xomolix
6. Contents of the pack and other information

1. What Xomolix is and what it is used for

Xomolix 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 in adults when they receive morphine based painkillers after an operation.

2. What you need to know before you use Xomolix

Do not use Xomolix:
- 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 nurse before using Xomolix 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)
- 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 Xomolix

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do not take Xomolix 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, halofantrine
Heartburn	Cisapride
Infection	Pentamidine
Nausea (feeling sick) or vomiting	Domperidone
Opiod dependence; pain	Methadone

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

Droperidol, the active ingredient in Xomolix, 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.

Xomolix with alcohol

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

Pregnancy and breast-feeding

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

If you are breast-feeding and are going to take Xomolix then it is recommended that you receive only one administration of Xomolix. 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 Xomolix.

3. How to use Xomolix

Xomolix will be given to you by your doctor by an injection into a vein.
The amount of Xomolix and the way in which it is given will depend on the situation. Your doctor will determine how much Xomolix you need.

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 kidney and liver impairment.

Use in children and adolescents
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. Xomolix 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:

Common side effects (likely to affect fewer than 1 in 10 people but more than 1 in 100)

- Drowsiness
- Low blood pressure

Uncommon side effects (likely to affect fewer than 1 in 100 people but 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 fewer than 1 in 1,000 people but 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 fewer 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
- 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:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xomolix

- 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 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.
- Compatibility of 5 mg droperidol with 100 mg morphine sulphate in 50 ml 0.9% sodium chloride has been demonstrated in plastic syringes (14 days at room temperature). 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 Xomolix 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 Xomolix 0.5 mg/ml contains

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

What Xomolix looks like and contents of the pack

Xomolix is a clear, colourless solution for injection.

The solution is contained in amber coloured glass ampoules. Each ampoule contains 2.5 millilitres of solution and ampoules are packaged in cartons containing 10 ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder	**Manufacturer**
Kyowa Kirin Holdings B.V. Bloemlaan 2 2132NP Hoofddorp The Netherlands	Sirton Pharmaceuticals SPA Piazza XX Settembre 2 22079 Villa Guardia Como Italy

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

France:	Droleptan 0,5 mg/mL
Belgium, The Netherlands, Luxembourg:	Xomolix 0,5 mg/ml
Italy:	Dridol
Cyprus, Greece, Ireland:	Xomolix 0,5 mg/ml
Germany:	Xomolix 0,5 mg/ml Injektionslösung

This leaflet was last revised in October 2018.