Package leaflet: Information for the user

Xomolix 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.
- 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 are given Xomolix
3. How you will be given 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 for injection containing the active substance droperidol, which belongs to a group of antipsychotics called butyrophenone derivatives. Xomolix 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 Xomolix

You should not be given Xomolix if you:
- are allergic to droperidol, or any of the other ingredients of this medicine (listed in section 6).
- 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
Talk to your doctor or nurse before using Xomolix:
- 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 vomiting or diarrhoea
- if you are taking 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, 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 Xomolix

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, as a number of medicines cannot be mixed with droperidol.

You should not be given Xomolix if you are taking any of the following medicines since the combination increases the risk of irregular heart beat which may lead to heart attack:

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 taking Xomolix since the risk of movement disorders induced by these medicines is increased.

Other medicines that may affect or be affected when used concomitantly with Xomolix.
Droperidol, the active substance in Xomolix:
- can increase the effects of sedatives such as barbiturates, benzodiazepines and morphine based products
- can increase the effects of medication used to lower high blood pressure
- can increase the effects of a number of other medicines e.g. certain antifungals, antivirals, and antibiotics

You should talk to your doctor or nurse if you are taking any of these medicines.

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

Pregnancy, breast-feeding and fertility
If you are pregnant, inform your doctor who will decide if you should receive Xomolix.

The following symptoms may occur in newborn babies, of mothers that have used Xomolix 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 you may need to contact your doctor.

If you are breast-feeding and will be given Xomolix, the treatment will be limited to only one administration. 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.

Xomolix contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per 1ml, i.e. essentially 'sodium-free'.

3. How you will be given 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 based on a number of things including your weight, age and medical condition.

If you have any further questions on the use of this medicine, 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 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:

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)

- Confusion
- Agitation
- Irregular heartbeat
- Rash

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
- 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 via:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
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 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 this medicine 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 contains
- The active substance is droperidol, each millilitre of solution contains 2.5 mg droperidol.
- The other ingredients are mannitol, tartaric acid, sodium hydroxide, 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 1 millilitre of solution and packaged in cartons containing 10 ampoules

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder (UK)	**Marketing Authorisation Holder (Ireland)**	**Manufacturer**
Kyowa Kirin Ltd Galabank Business Park Galashiels TD1 1QH United Kingdom	Kyowa Kirin Holdings B.V. Bloemlaan 2 2132NP Hoofddorp The Netherlands	Delpharm Tours rue Paul Langevin Chambray-les-Tours France

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

Xomolix
Austria, France, Germany, Greece, Spain, Hungary, Ireland, Italy, Portugal, Slovenia, Slovak Republic, UK.

Dehydrobenzperidol
Belgium, Denmark, Finland, Luxembourg, Netherlands

Dridol
Iceland, Norway, Sweden

This leaflet was last revised in October 2018.