PACKAGE LEAFLET: INFORMATION FOR THE USER

Kytril 1 mg/1 ml solution for injection
Kytril 3 mg/3 ml solution for injection

Granisetron

Read all of this leaflet carefully before you start taking 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, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Kytril is and what it is used for

Kytril contains the active substance granisetron. This belongs to a group of medicines called '5-HT_3 receptor antagonists' or 'anti-emetics'.

Kytril is used to prevent or treat nausea and vomiting (feeling and being sick) caused by other medical treatments, such as chemotherapy or radiotherapy for cancer, and by surgery.

The solution for injection is for use in adults and children from 2 years old.

2. What you need to know before you are given Kytril

Do not use Kytril

- if you are allergic (hypersensitive) to granisetron or any of the other ingredients of Kytril (listed in Section 6: Further information).

If you are not sure, talk to your doctor, nurse or pharmacist before having the injection.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Kytril, especially if you:
- are having problems with your bowel movements because of a blockage of your gut (intestines)
- have heart problems, are being treated for cancer with a medicine that is known to damage your heart or have problems with levels of salts, such as potassium, sodium or calcium, in your body (electrolyte abnormalities)

- are taking other '5-HT_3 receptor antagonist' medicines. These include dolasetron, ondansetron used like Kytril in the treatment and prevention of nausea and vomiting.

Serotonin Syndrome is an uncommon but potentially life-threatening reaction that can occur with granisetron (see section 4). It can cause serious changes in how your brain, muscles, and digestive system work. The reaction *can occur if you take Kytril alone but* it is more likely to occur if you take Kytril with certain other medicines (in particular fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, venlafaxine, duloxetine). The risk of serotonin syndrome is also increased if you are taking buprenorphine-containing medicinal products or other opioids. Be sure to tell your doctor, nurse or pharmacist all the medicines you are taking.

Other medicines and Kytril

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because Kytril can affect the way some medicines work. Also some other medicines can affect the way this injection works.

In particular, tell your doctor or nurse if you are taking or might have taken any other medicines:
- medicines used to treat an irregular heartbeat other '5-HT_3 receptor antagonist' medicines such as dolasetron or ondansetron (see "Warnings and precautions" above)
- phenobarbital, a medicine used to treat epilepsy
- a medicine called ketoconazole used in the treatment of fungal infections
- the antibiotic erythromycin used to treat bacterial infections
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety. Examples are fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety. Examples are venlafaxine, duloxetine.
- Buprenorphine-containing medicinal products or other opioids

Pregnancy and breast-feeding

You should not have this injection if you are pregnant, trying to get pregnant or are breast-feeding, unless your doctor has told you to.

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

Driving and using machines

Kytril is not likely to affect your ability to drive or use any tools or machines.

Kytril contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose (1mg/1ml; 3 mg/3ml), that is to say essentially 'sodium-free'.

3. How Kytril will be given

The injection will be given to you by a doctor or nurse. The recommended dose of Kytril varies from one patient to another. It depends on your age, weight, and whether you are being given the medicine to prevent, or treat, nausea and vomiting. The doctor will work out how much to give you.

Kytril can be given as an injection into the veins (intravenous).

Prevention of feeling or being sick following radio- or chemotherapy

You will be given the injection before your radio- or chemotherapy starts. The injection into your veins will take between 30 seconds and 5 minutes and the dose will usually be between 1 and 3 mg. The medicine may be diluted before it is injected.

Treatment of feeling or being sick following radio- or chemotherapy

The injection will take between 30 seconds and 5 minutes and the dose will usually be between 1 and 3 mg. The medicine may be diluted before it is injected into your veins. You may be given more injections to stop your sickness after the first dose. There will be at least 10 minutes between each injection. The most Kytril you will be given is 9 mg a day.

Combination with steroids

The effect of the injection may be improved by the use of medicines called adrenocortical steroids. The steroid will be given either as a dose between 8 and 20 mg dexamethasone before your radio- or chemotherapy or as 250 mg methyl-prednisolone, which will be given both before and after your radio- or chemotherapy.

Use in children in the prevention or treatment of feeling or being sick following radio- or chemotherapy

Children will be given Kytril by injections into the vein as described above with the dose depending on the child's weight. The injections will be diluted and be given before radio- or chemotherapy and will take 5 minutes. Children will be given a maximum of 2 doses a day, at least 10 minutes apart.

Treatment of feeling or being sick following surgery

The injection into your veins will take between 30 seconds and 5 minutes and the dose will usually be 1 mg. The most Kytril you will be given is 3 mg a day.

Use in children in the prevention or treatment of feeling or being sick following surgery

Children should not be given this injection to treat sickness or the feeling of sickness after surgery.

If you are given too much Kytril

Because the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. However, if you are worried talk to your doctor or nurse. Symptoms of overdose include mild headaches. You will be treated depending on your symptoms.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice the following problem you must see a doctor straight away:

- allergic reactions (anaphylaxis). The signs may include swelling of the throat, face, lips and mouth, difficulty in breathing or swallowing.
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- serotonin syndrome. serotonin syndrome. The signs may include diarrhoea, nausea, vomiting, high temperature and blood pressure, excessive sweating and rapid heartbeat, agitation, confusion, hallucination, shivering, muscle shakes, jerks or stiffness, loss of coordination and restlessness. This reaction can occur if you take Kytril alone or, more likely, with certain other medicinal products (see "Warnings and Precautions").

Other side effects that may be experienced while taking this medicine are:

Very common: affects more than 1 user in 10 people
- headache
- constipation. Your doctor will monitor your condition.

Common: may affect up to 1 in 10 people
- problems sleeping (insomnia)
- changes in how your liver is working shown by blood tests
- diarrhoea.

Uncommon: may affect up to 1 in 100 people
- skin rashes or an allergic skin reaction or "nettle-rash" or "hives" (urticaria). The signs may include red, raised itchy bumps
- changes in the heartbeat (rhythm) and changes seen on ECG readings (electrical recordings of the heart)
- abnormal involuntary movements, such as shaking, muscle rigidity and muscle contractions

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

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

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

5. How to store Kytril

Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and/or ampoule after EXP. The expiry date refers to the last day of that month. Kytril should be stored protected from light.

Following dilution, the diluted solution should be stored between 2°C and 8°C and used within 24 hours of dilution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and information

What Kytril contains

The active substance is granisetron.
Each ml solution for injection contains 1 mg of granisetron (as hydrochloride).

The other ingredients are sodium chloride, water for injections, citric acid monohydrate, hydrochloric acid and sodium hydroxide for pH (acidity) adjustment.

What Kytril looks like and contents of the pack

Kytril solution is a clear, colourless liquid supplied in 1 and 3 ml nominal volume colourless glass ampoules. Each pack contains either 1 or 5 ampoules. Not all pack sizes may be marketed.
Each 1 ml Kytril solution contains 1 mg of granisetron (as the hydrochloride).
Each 1 ml ampoule contains 1mg of granisetron (as the hydrochloride).
Each 3 ml ampoule contains 3 mg of granisetron (as the hydrochloride).

Preparation of dilution
For single use only. Dilute before use. The product requires dilution prior to delivery as either injection or infusion

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Atnahs Pharma Netherlands B.V.
Copenhagen Towers
Ørestads Boulevard 108, 5.tv
DK-2300 København S
Denmark

Manufacturer

Cenexi
52, rue M. et J. Gaucher
94120 Fontenay-sous-Bois
France

This medicine product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Belgium, Czech Republic, Estonia, France, Ireland, Italy, Netherlands, Slovenia, Spain and United Kingdom: Kytril

Germany: Kevatril

This leaflet was last revised in March 2025.

Other sources of information.

Detailed information on this medicine is available on the Health Products Regulatory Agency (HPRA) website: http://www.hpra.ie