

PACKAGE LEAFLET: INFORMATION FOR THE USER

Kytril 1 mg film-coated tablets

Kytril 2 mg film-coated tablets

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
2. What you need to know before you take Kytril
3. How to take Kytril
4. Possible side effects
5. How to store Kytril
6. Contents of the pack and information

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-HT₃ receptor antagonists' or 'anti-emetics'. These tablets are only for use in adults.

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.

2. What you need to know before you take Kytril

Do not take Kytril tablets

- if you are allergic (hypersensitive) to granisetron or any of the other ingredients of Kytril (listed in section 6: Further information and "Important Information about some of the ingredients Kytril below").

If you are not sure, talk to your doctor, nurse or pharmacist before taking these tablets.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using these tablets, 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-HT₃ 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 medications (in particular fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, venlafaxine, duloxetine). Be sure to tell your doctor, nurse or pharmacist all the medicines you are taking.

Children

Children should not take these tablets.

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 these tablets work.

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-HT₃ 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.

Pregnancy and breast-feeding

You should not take these tablets 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 has no or negligible effect on your ability to drive or use any tools or machines.

Kytril contains

Kytril contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Kytril is essentially 'sodium free' as it contains less than 1 mmol sodium (23 mg) per dose (2 mg).

3. How to take Kytril

Always take this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

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.

Prevention of feeling or being sick

Your first dose of Kytril will usually be given an hour before your radio- or chemotherapy. The dose will be taken either as:

- one 1 mg tablet twice a day or
- two 1 mg tablets once a day or
- one 2 mg tablet once a day

for up to a week after your radio- or chemotherapy.

Treatment of feeling or being sick

The dose will usually be taken either as:

- one 1 mg tablet twice a day or
- two 1 mg tablets once a day or
- one 2 mg tablet once a day.

If you take more Kytril than you should

If you think you have taken too many of the tablets talk to your doctor or nurse. The symptoms of overdose include mild headaches. You will be treated depending on your symptoms.

If you forget to take Kytril

If you think you have forgotten to take your medicine speak to your doctor or nurse.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Kytril

Do not stop taking your medicine before the treatment is finished. If you do stop taking your medicine, your symptoms may return.

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.

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

Very common: may affect more than 1 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
- Serotonin Syndrome. The signs may include diarrhea, nausea, vomiting, high temperature and blood pressure, excessive sweating and rapid heartbeat, agitation, confusion, hallucination, shivering, muscles shakes, jerks or stiffness, loss of coordination and restlessness.

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.

HPRA Pharmacovigilance
Earlsfort Terrace
IRL-Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
email: 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 blister and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 other information

What Kytril contains

The active substance is granisetron.

Each 1 mg film-coated tablet contains 1 mg granisetron (as the hydrochloride).

Each 2 mg film-coated tablet contains 2 mg granisetron (as the hydrochloride).

The other ingredients are:

Lactose monohydrate

Hypromellose

Sodium starch glycolate

Cellulose, microcrystalline

Magnesium stearate

Film-coat:

Hypromellose

Titanium dioxide (E171)

Macrogol 400

Polysorbate 80

What Kytril looks like and contents of the pack

The tablets are white to almost white triangular biconvex tablets imprinted with K1 on one side.
The tablets are white to almost white triangular biconvex tablets imprinted with K2 on one side.
Opaque PVC blisters sealed with an aluminium foil containing 2 or 10 tablets (1 mg) or 1, 5 or 10 tablets (2 mg). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Atnahs Pharma Netherlands B.V.
Strawinskylaan 3127
1077ZX Amsterdam
The Netherlands

Manufacturer

IL CSM Clinical Supplies Management
Marie-Curie-Strasse 8
Lörrach
Baden-Württemberg
79539, Germany
Or
Waymade Plc
Sovereign House
Miles Gray Road
Basildon
Essex SS14 3FR
United Kingdom

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

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

Germany: Kevatril

This leaflet was last revised in March 2019

Other sources of information.

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