

Kytril® 1 mg Film-coated Tablets
Kytril® 2 mg Film-coated Tablets
Granisetron

Roche

Read all of this leaflet carefully before you start taking this medicine.

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1. What Kytril is and what it is used for
2. Before you take Kytril
3. How to take Kytril
4. Possible side effects
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6. Further information

1. WHAT KYTRIL IS AND WHAT IT IS USED FOR

Kytril contains a medicine called 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. 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 of Kytril below').

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

Take special care with Kytril

Check with your doctor, nurse or pharmacist before using these tablets, 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
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Children

Children should not take these tablets.

Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken 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, nurse or pharmacist if you are taking the following medicines:

- medicines used to treat an irregular heartbeat, other '5-HT₃ receptor antagonist' medicines such as dolasetron or ondansetron (see 'Take special care with Kytril' 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.

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.

Ask your doctor, nurse or pharmacist for advice before taking any medicine.

Driving and using machines

Kytril has no or negligible affect on your ability to drive or use any tools or machines.

Important information about some of the ingredients of Kytril

This medicine 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.

3. HOW TO TAKE KYTRIL

Always take Kytril exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

The 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 either one or two 1 mg tablets 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 either one or two 1 mg tablets or one 2 mg tablet once a day, but your doctor may decide to increase your dose to up to nine 1 mg tablets 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, Kytril 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: affects more than 1 user in 10

- headache.
- constipation. Your doctor will monitor your condition.

Common: affects 1 to 10 users in 100

problems sleeping (insomnia)

- changes in how your liver is working shown by blood tests
- diarrhoea

Uncommon: affects 1 to 10 users in 1,000

- 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. HOW TO STORE KYTRIL

Keep out of the reach and sight of children.

The tablets should not be used 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Kytril contains

The active substance is granisetron.

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

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

The other ingredients are microcrystalline cellulose (E460), sodium starch glycollate, hypromellose (E464), lactose monohydrate, magnesium stearate (E572), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433).

What Kytril looks like and contents of the pack

Kytril 1 mg Film-coated Tablets are triangular biconvex tablets. They are white to almost white in colour imprinted with K1 on one side.

Kytril 2 mg Film-coated Tablets are triangular biconvex tablets. They are white to almost white in colour imprinted with K2 on one side.

These tablets are supplied in blister packs containing either ten 1mg tablets or five 2mg tablets. Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names: Austria, Belgium, Bulgaria, Czech Republic, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, , Slovenia, Spain, Sweden and United Kingdom: Kytril

Germany: Kevatril

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