

Applicant / PHCR:	Pharmaco Distribution (Pty) Ltd, South Africa	MODULE 1
Proprietary Name:	KYTRIL® 1 MG ORAL	1.3.2
Dosage Form / Strength:	Each Tablet contains Granisetron Hydrochloride Equivalent to Granisetron 1,0 mg	
Registration Number:	28/5.7.2/0162	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

KYTRIL 1 mg ORAL Tablet

KYTRIL 2 mg ORAL Tablet

KYTRIL 1 mg/1 mL Injection

KYTRIL 3 mg/3 mL Injection

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. 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 or pharmacist.

1. WHAT KYTRIL CONTAINS

1 mg and 2 mg Tablets:

Film-coated tablets containing 1 mg or 2 mg of granisetron (free base equivalent).

Other ingredients: hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate,

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microcrystalline cellulose, opadry white, polyethylene glycol, polysorbate 80, and titanium dioxide.

Injection:

Ampoules contain sterile, clear solution equivalent to 1 mg of granisetron (free base equivalent) in 1 ml or 3 mg of granisetron (free base equivalent) in 3 ml.

Other ingredients: citric acid, hydrochloric acid, sodium chloride, sodium hydroxide and water for injections.

2. WHAT KYTRIL IS USED FOR

KYTRIL contains a medicine called granisetron. This belongs to a group of medicines called “5-HT₃ receptor antagonists” which act as “anti-emetics”.

KYTRIL is used to prevent or treat nausea and vomiting (feeling and being sick) after having an operation or other treatments, such as chemotherapy or radiotherapy for cancer.

3. BEFORE TAKING KYTRIL

Do not use KYTRIL if you are allergic (hypersensitive) to:

- Granisetron or any of the other ingredients of KYTRIL.
- Other 5-HT₃ receptor antagonist medicines. These include dolasetron, ondansetron, palonosetron and tropisetron.

You must not be given KYTRIL if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before having KYTRIL.

Take special care with KYTRIL

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Check with your doctor, nurse or pharmacist before having KYTRIL if:

- You are having problems with your bowel movements because of a blockage in your gut (intestines).
- KYTRIL has been prescribed for a child under 12 years of age. KYTRIL is not recommended for use by children under 12 years of age.

If the above applies to you, or if you are not sure, talk to your doctor, nurse or pharmacist before getting KYTRIL.

Pregnancy and breastfeeding

You should not be given KYTRIL if you are pregnant, trying to get pregnant or breast feeding unless your doctor has told you to.

If you are pregnant or breast feeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery

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

Important information about some of the ingredients of KYTRIL

KYTRIL injection is essentially “sodium free” as it contains less than 1 mmol sodium (23 mg) per 3 mg dose.

KYTRIL tablets contain lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have intolerance to some sugars), talk to your doctor before taking this medicine.

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Taking other medicines with KYTRIL

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because KYTRIL can affect the way some medicines work. Also, some medicines can affect the way KYTRIL works.

If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of KYTRIL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO TAKE KYTRIL

Always take KYTRIL exactly as your doctor has told you. You should check with your doctor if you are not sure.

KYTRIL tablets:

The usual dose is either:

- One 1 mg tablet one hour or less before the start of the medical treatment that makes you feel or be sick and another 1 mg tablet 12 hours later. **Or**
- One 2 mg tablet within one hour or less before the start of the medical treatment that makes you feel or be sick.

Do not take more tablets than your doctor has told you to.

KYTRIL injection will be given to you by your doctor or nurse. It will be given to you either as a slow injection into one of your veins (called an “intravenous infusion”). The injection usually takes 30 seconds and the infusion usually takes five minutes.

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

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will work out how much to give you.

If you take more KYTRIL than you should

KYTRIL Tablets: If you take more KYTRIL than you should, talk to a doctor straight away.

KYTRIL injection: because KYTRIL will be given to you by a doctor or nurse it is unlikely that you will be given too much or that you will miss a dose. However, if you are worried, talk to your doctor or nurse.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take KYTRIL

- If you forget to take a dose, and you feel sick, take it as soon as you remember.
- However, do not take a double dose (two doses at the same time) to make up for the forgotten dose.

5. POSSIBLE SIDE-EFFECTS

Like all medicines, KYTRIL can cause side effects, although not everyone will get them.

Allergic reactions

If you have an allergic reaction, **stop taking KYTRIL and tell your doctor straight away.** The signs may include:

- Swelling of the throat, face, lips and mouth. This may make it difficult to breathe or swallow.
- Sudden swelling of the hands, feet or ankles.

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Other possible side effects:

- Constipation
- Changes in how your liver is working (shown by blood tests).
- Abnormal (uncontrollable) body movements, shaking or muscular stiffness.
- Skin rashes.
- Headache.

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

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF KYTRIL

Store all medicines out of reach of children.

- Store below 30 °C.
- Ampoules removed from the pack should be stored and protected from direct sunlight.

Do not freeze.

- Do not use after the expiry date stated on the pack.
- Return unused or expired medicines to your pharmacist for safe disposal.

7. PRESENTATION OF KYTRIL

KYTRIL 1 mg ORAL: 10 tablets in a blister strip placed in a carton box.

KYTRIL 2 mg ORAL: 5 tablets in a blister trip placed in a carton box.

KYTRIL 1 mg/1 mL: 5 ampoules in a box.

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KYTRIL 3 mg/3 mλ: 5 ampoules in a box.

8. IDENTIFICATION OF KYTRIL

KYTRIL 1 mg ORAL - each tablet is presented as a white to almost white, triangular, biconvex, film-coated tablet embossed with "K1" on one face.

KYTRIL 2 mg ORAL - each tablet is presented as a white to almost white, triangular, biconvex, film-coated tablet, embossed with "K2" on one face.

KYTRIL 1 mg/1 mλ - each ampoule contains a clear, colourless sterile solution.

KYTRIL 3 mg/3 mλ - each ampoule contains a clear, colourless sterile solution.

9. REGISTRATION NUMBERS

KYTRIL 1 mg ORAL: 28/5.7.2/0162

KYTRIL 2 mg ORAL: 30/5.7.2/0346

KYTRIL 1 mg/1 mλ: 31/5.7.2/0082

KYTRIL 3 mg/3 mλ: Y/5.7.2/272

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Pharmaco Distribution (Pty) Ltd.

3 Sandown Valley Crescent,

South Tower, 1st Floor,

Sandton, 2196,

South Africa

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