Kytril® Injection

pronounced (Kai-tril)

contains the active ingredient granisetron hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about KYTRIL ampoules for injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given KYTRIL against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What KYTRIL is used for

KYTRIL contains the active ingredient granisetron.

KYTRIL belongs to a group of medicines called anti-emetics.

KYTRIL is given to stop you feeling sick (nauseous) or being sick (vomiting). It is especially useful when you need to have medical treatment that may cause you to feel or be sick, for example, chemotherapy, radiotherapy or surgery.

Ask your doctor if you have any questions about why KYTRIL has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you are given KYTRIL

When you must not be given it

You must not be given KYTRIL if you have an allergy to:

- any medicine containing granisetron
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or breathing difficulty; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you are not sure whether you should be given KYTRIL, talk to your doctor.

Before you are given it

Tell your doctor if:

- you have allergies to any other medicines, foods, preservatives or dyes.
- you have had an allergic reaction with other medicines used to prevent or treat nausea and vomiting, such as ondansetron and tropisetron. You may have an allergic reaction to KYTRIL as well.
- you have severe constipation.
- you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits of using KYTRIL while you are pregnant or breast-feeding.

• you have been given KYTRIL before, and you became unwell.

You may need to be given another medicine instead.

• you have a heart condition related to changes in the rhythm or rate of your heart beat.

If you have not told your doctor about any of the above, tell him/her before you are given KYTRIL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and KYTRIL may interfere with each other. These include:

- phenobarbitone, a medicine used to treat epilepsy.
 Phenobarbitone may be affected by KYTRIL or may affect how well KYTRIL works. You may need different amounts of your medicine, or you may need to take a different medicine.
- medicines that can affect the serotonin levels in your body. These may include: some antibiotics, medicines used to treat depression, medicines that treat or prevent pain, some medicines to treat Parkinson's disease, medicines to treat

obesity; and medicines used to treat attention hyperactivity disorder.

Your doctor and pharmacist have more information on medicines to be careful of or avoid while being given KYTRIL.

How KYTRIL is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

How it is given

KYTRIL injection is given as a fast or slow injection into a vein (intravenous 'drip'). It must only be given by a nurse or doctor.

If you receive too much (overdose)

As KYTRIL is given to you in a hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose. However, if you experience severe side effects tell your doctor immediately.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

While you are being given KYTRIL

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are being given KYTRIL.

Tell your doctor immediately if you become pregnant while you are being treated with KYTRIL. Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how KYTRIL affects you.

Be careful when drinking alcohol while you are being given KYTRIL.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are being given KYTRIL.

If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with KYTRIL.

This medicine helps most people with nausea and vomiting, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- unusual tiredness or weakness
- · dizziness or light-headedness

- nervousness
- drowsiness
- difficulty in sleeping
- abdominal pain
- constipation
- diarrhoea
- altered taste
- fever
- skin rash.

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain
- changes in your heart beat
- severe dizziness or fainting
- seizures
- symptoms of serotonin syndrome such as fever, sweating, fast heartbeat, agitation or confusion and loss of muscle coordination, which may lead to loss of consciousness
- symptoms of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using KYTRIL

Storage

KYTRIL ampoules for injection will be stored in the pharmacy or on the ward. The ampoules are kept in a cool dry place, protected from light where the temperature stays below 30° C.

Product description

What it looks like

KYTRIL is a clear solution for injection in a glass ampoule.

KYTRIL ampoules come in the following pack sizes:

- 1 mg/1 mL: pack containing 5 ampoules
- 3 mg/3 mL: pack containing 1 ampoule

KYTRIL is also available as a 2 mg tablet.

Ingredients

Active Ingredient

KYTRIL ampoules for injection contain the active ingredient granisetron.

- each 1 mg/1 mL ampoule contains 1 mg of granisetron
- each 3 mg/3 mL ampoule contains 3 mg of granisetron

Inactive Ingredients

- sodium chloride 0.9% in water for injection
- citric acid monohydrate
- sodium hydroxide
- hydrochloric acid.

KYTRIL ampoules for injection do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Atnahs Pharma Australia Pty Ltd Level 10 10 Shelley Street, SYDNEY, NSW, 2000, Australia

Supplier

KYTRIL is supplied by:

Clinect Pty Ltd 120 - 132 Atlantic Drive Keysborough VIC 3173 Australia Customer enquiries: 1 800 899 005

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers (AUST R):

- 1 mg/1 mL injection: 115317
- 3 mg/ 3 mL injection: 97550

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