

PACKAGE LEAFLET: INFORMATION FOR THE USER

Granisetron Combino Pharm 3 mg/3 ml concentrate for solution for infusion Granisetron

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

What is in this leaflet:

1. What Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion is and what it is used for
2. What you need to know before you use Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion
3. How to use Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion
4. Possible side effects
5. How to store Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion
6. Contents of the pack and other information

1. WHAT Combino Pharm 3 mg/3 ml, concentrate for solution for infusion IS AND WHAT IT IS USED FOR

Granisetron belongs to a group of medicines called 5-HT₃ receptor antagonists which act as anti-emetics. It is used to prevent and treat nausea (feeling sick) and vomiting (being sick).

Granisetron is used to stop you from feeling or being sick after certain types of treatment, for example, chemotherapy or radiotherapy. ...

2. WHAT YOU NEED TO KNOW BEFORE YOU USE Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion

Do not use Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion:

- if you are allergic granisetron or any of the other ingredients of this medicine (listed in section 6)

Take special care with Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion

- if you are allergic to granisetron or other antiemetic products
- if you have been told by a doctor that your bowels don't work properly
- if you have any pain in your abdomen (tummy) or your abdomen feels distended or swollen
- if you have severe constipation

Using other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

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

You should not be given this medicine if you are pregnant or are breast feeding unless your doctor has specifically recommended it.

Driving and using machines

There is no data about how Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion affects driving or using machines. Therefore, you should not perform tasks requiring special attention until you were sure that the product is well tolerated.

Important information about some of the ingredients of Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion

The product contains less than 23 mg (1 mmol) of sodium per 3 ml dose, therefore it can be considered 'sodium free'.

3. HOW TO USE Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion

Your medicine will be given to you by your doctor or nurse:

- In **adults** as an intravenous infusion diluted to a volume of 20 - 50ml and given over five minutes.
- In **children** as an intravenous infusion diluted in 10 to 30ml of fluid given over five minutes.

Granisetron 3 mg/3 ml is usually given before the treatment that is likely to make you feel sick, although it can be given afterwards to stop any sickness you may be having.

The usual dosage:

- In **adults** 3 milligrams (mg) before chemotherapy or radiotherapy. Two further doses each of 3mg may be given within 24 hours if needed. No more than 9mg should be given in one day.
- In **children** 0.04mg for each kilogram (kg) of body weight (up to 3mg) to prevent sickness before chemotherapy or radiotherapy. For example a 20kg child would have 0.8mg of Granisetron. The same dose may be given after treatment to stop sickness. No more than two doses should be given within 24 hours.

If you take use more Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion than you should

Since you will be given the injection 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following uncommon (more than 1 patient in 1000 and less than 1 patient in 100) may occur:

Nervous system disorders

Headache

Gastrointestinal disorders

Nausea, constipation, diarrhea, vomiting.

General disorders

General weakness

The following rare (more than 1 patient in 10000 and less than 1 patient in 1000) may occur:

Psychiatric disorders

Anorexia

Nervous system disorders

Coma, extrapyramidal disorders (motor system disorders)

Liver disorders

Elevation of liver enzymes

Skin and subcutaneous tissue disorders

Hypersensitivity reactions of the skin as itching and rash

General disorders

Severe hypersensitivity reactions. You should tell your doctor straight away if you become short of breath or get a swollen face. These reactions are rare but need urgent medical treatment

If you are having blood tests, tell your doctor you have been given Granisetron 3 mg/3 ml because it sometimes causes changes in tests of liver function.

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 nurse.

5. HOW TO STORE Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion

Do not freeze. Keep in the original container.

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

Do not use Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion after the expiry date which is stated on the ampoule. The expiry date refers to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion contains

- The active substance is granisetron (as hydrochloride)
- The other ingredients are citric acid monohydrate, sodium chloride, sodium hydroxide and water for injections

What Granisetron Combino Pharm 3 mg/3 ml, concentrate for solution for infusion looks like and contents of the pack

Clear and colorless solution

Each box contains 5 clear glass ampoules of 3 ml.

Marketing Authorisation Holder

Combino Pharm SL
Fructuós Gelabert, 6-8
08970 Sant Joan Despí
Spain

Manufacturer

B.Braun Medical SA.
C/ Ronda Los Olivares nº5
Polígono Industrial Los Olivares
23009-Jaen
SPAIN

This leaflet was last approved in {MM/YYYY}.

The following information is intended for medical or healthcare professionals only:

Preparing the infusion: To prepare a dose of 3mg, 3ml is withdrawn from the ampoule and diluted either to 15ml with infusion fluid to a total volume of 20 to 50ml in any of the following solutions: 0.9% w/v Sodium Chloride Injection; 0.18% w/v Sodium Chloride and 4% w/v Glucose Injection; 5% w/v Glucose Injection; Hartmann's Solution for Injection; Sodium Lactate Injection; or 10% Mannitol Injection (for infusion). No other diluents should be used.

Ideally, intravenous infusions of granisetron should be prepared at the time of administration. After dilution (see above) the shelf life is 24 hours when stored at ambient temperature in normal indoor illumination protected from direct sunlight. It must not be used after 24 hours. If to be stored after preparation, granisetron infusions must be prepared under appropriate aseptic conditions.

As a general precaution, granisetron should not be mixed in solution with other drugs.