Package leaflet: Information for the patient

Ondansetron Kabi 0.08 mg/ml solution for infusion
Ondansetron Kabi 0.16 mg/ml solution for infusion
ondansetron

Read all of this leaflet carefully before you are given 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ondansetron Kabi is and what it is used for

Ondansetron Kabi belongs to a group of medicines called anti-emetics, medicines against feeling sick or being sick. Some medical treatment with medicines for treatment of cancer (chemotherapy) or radiotherapy can make you feel sick (nausea) or be sick (vomiting). Also after surgical treatment you can feel sick (nausea) or be sick (vomiting). Ondansetron Kabi may help to prevent or to stop these effects.

2. What you need to know before you are given Ondansetron Kabi

Do not use Ondansetron Kabi
- if you are allergic to ondansetron or other selective $5HT_3$ receptor antagonists (e.g. granisetron, dolastron) or any of the other ingredients of this medicine (listed in section 6).
- if you are treated with apomorphine (used to treat Parkinson's disease)

Warnings and precautions
Talk to your doctor, nurse or pharmacist before using Ondansetron Kabi.
- if you have had allergy to other medicines against feeling sick or being sick, such as granisetron or palonosetron.
- if you have a blockage in your gut or suffer from severe constipation. This medicine can block the mobility of the lower gut.
- if you have any liver problems.
- if you have undergone surgery to remove the palatine tonsils situated at the back of the throat (adenotonsillar surgery).
- if you have ever had heart problems, including an uneven heartbeat (arrhythmias). This medicine prolongs the QT interval (ECG sign of delayed repolarization of the heart

following a heartbeat with the risk of life-threatening arrhythmias) in a dose-dependent manner.
- if you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

Other medicines and Ondansetron Kabi
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

- If you are taking tramadol (painkiller): ondansetron may reduce the analgesic effect of tramadol.
- If you are taking phenytoin, carbamazepine (anti-epileptics) or rifampicin (antibiotic for tuberculosis): the ondansetron blood concentrations are decreased.
- If you are taking cardiotoxic medicines (anthracyclines (cancer antibiotics such as doxorubicin, daunorubicin) or trastuzumab, a cancer medicine), antibiotics (such as erythromycin), antifungals (such as ketoconazole), antiarrhythmics (such as amiodarone) and beta blockers (medicines that slow heart rate such as atenolol or timolol): use of ondansetron with other QT prolonging medicines may result in an additional QT prolongation, like increase the risk of arrhythmias.
- If you are taking other serotonergic medicines such as selective serotonin reuptake inhibitors (SSRIs) or serotonin noradrenaline reuptake inhibitors (SNRIs) like sertraline or duloxetine (both are antidepressants): there are case reports describing patients with the so-called serotonin syndrome (such as hypervigilance (alertness) and agitation, increased heart rate and blood pressure, tremor and overresponsive reflexes) following the use of ondansetron at the same time with other serotonergic medicines.
- If you are taking apomorphine (medicine to treat Parkinson's disease): apomorphine must not be used together with ondansetron, as there are case reports of profound hypotension (low blood pressure) and loss of consciousness when both medicines are administered at the same time.

Pregnancy and breast-feeding
You should not use Ondansetron Kabi during the first trimester of pregnancy. This is because Ondansetron Kabi can slightly increase the risk of a baby being born with cleft lip and/or cleft palate (openings or splits in the upper lip and/or the roof of the mouth).
If you are already pregnant or breast-feeding, think you might be pregnant or are planning to have baby, ask your doctor or pharmacist for advice before using this medicine.
If you are a woman of childbearing potential you may be advised to use effective contraception.

Ondansetron passes into mother's milk. Therefore mothers receiving ondansetron should not breast-feed.

Driving and using machines
Ondansetron has no effect on the ability to drive or use machines.

Ondansetron Kabi contains sodium
This medicine contains 357 mg sodium (main component of cooking/table salt) in each 100 ml bottle. This is equivalent to 17.9 % of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 178.5 mg sodium (main component of cooking/table salt) in each 50 ml bottle. This is equivalent to 8.9 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ondansetron Kabi is given

Method of administration
This medicine is administered as intravenous infusion. It will usually be given by a doctor or a nurse.

Dosage
Adults (less than 75 years of age)
Your doctor will decide on the correct dose of ondansetron therapy for you.
The dose varies depending on your medicinal treatment (chemotherapy or surgery) and on your liver function.

In case of chemotherapy or radiotherapy the usual dose in adults is 8 – 32 mg ondansetron a day. A single dose greater than 16 mg must not be given.

For treatment of post-operative nausea and vomiting, usually a single dose of 4 mg ondansetron is administered. For prevention of post-operative nausea and vomiting usually a single dose of 4 mg ondansetron is administered.

C**hildren over 6 months and adolescents**
In case of chemotherapy the usual dose is a single intravenous dose of 5 mg/m^2 (body area) or 0.15 mg/kg (body weight) immediately before chemotherapy. The single intravenous dose must not exceed 8 mg. The total dose over 24 hours (given as divided doses) must not exceed the adult dose of 32 mg.

Children over 1 month and adolescents
- For treatment of post-operative nausea and vomiting the usual dose is of 0.1 mg/kg (body weight) up to a maximum of 4 mg.
- For prevention of post-operative nausea and vomiting the usual dose is of 0.1 mg/kg (body weight) up to a maximum of 4 mg. This will be given just before the operation.

Dosage adjustment
Elderly
In case of chemotherapy the initial dosage should not exceed 8 mg for patients 75 years of age or older.

Patients with hepatic impairment
In patients having liver problems the dose has to be adjusted to a maximum daily dose of 8 mg.

Patients with renal impairment or poor sparteine/debrisoquine metabolism
No alteration of daily dosage or frequency of dosing or route of administration is required.

Duration of treatment
Your doctor will decide on the duration of ondansetron therapy for you.

After intravenous administration of Ondansetron Kabi the therapy may be continued with ondansetron tablets or suppositories for up to 5 days.

If you received more Ondansetron Kabi than you should
Little is known at present about overdosage with ondansetron. Overdose increases the probability of side effects described in section 4. In a few patients, the following effects were observed after overdose: visual disturbances, severe constipation, low blood pressure, disturbance in heart rhythm and unconsciousness. In all cases, the symptoms disappeared completely.

Your doctor or nurse will give you or your child Ondansetron Kabi so it is unlikely that you or your child will receive too much. If you think you or your child have been given too much or have missed a dose, tell your doctor or nurse.

There is no specific antidote to ondansetron; for that reason, if overdose is suspected, only the symptoms should be treated.

Tell your doctor if any of these symptoms occur.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

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

Tell your doctor or nurse immediately if you experience any of the following:

Uncommon: may affect up to 1 in 100 people
- Chest pain, uneven heartbeat (arrhythmia which may be fatal in individual cases) and slow heartbeat (bradycardia)

Rare: may affect up to 1 in 1,000 people
- Immediate allergic reactions including life-threatening allergic reaction (anaphylaxis). These reactions may be: itchy rash, swelling of the eyelids, face, lips, mouth and tongue.

Not known: frequency cannot be estimated from the available data
- Myocardial ischemia
  Signs include: sudden chest pain or chest tightness.

Other side effects include:

Very common: may affect more than 1 in 10 people
- headache

Common: may affect up to 1 in 10 people
- constipation
- sensation of warmth or flushing
- irritation and redness at the site of injection

Uncommon: may affect up to 1 in 100 people

- low blood pressure, which can make you feel faint or dizzy
- fits
- unusual body movements or shaking
- hiccups
- interference with liver function tests

Rare: may affect up to 1 in 1,000 people
- feeling dizzy or light-headed
- blurred vision
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

Very rare: may affect up to 1 in 10,000 people
- temporary blindness (most resolved within 20 minutes)
- skin rash, e.g. red spots or lumps under the skin (hives) anywhere on the body which can transform into large blisters

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

For UK - The Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For Ireland – HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ondansetron Kabi

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

Do not use this medicine after the expiry date which is stated on the bottle label and carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.
Keep the bottles in the outer carton, in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ondansetron Kabi contains
- The active substance is ondansetron.

Ondansetron Kabi 0.08 mg/ml, 1 ml solution for infusion contains 0.08 mg ondansetron as ondansetron hydrochloride dihydrate.
Each bottle with 50 ml contains 4 mg ondansetron
Each bottle with 100 ml contains 8 mg ondansetron
Ondansetron Kabi 0.16 mg/ml, 1 ml solution for infusion contains 0.16 mg ondansetron as ondansetron hydrochloride dihydrate.
Each bottle with 50 ml contains 8 mg ondansetron

- The other ingredients are sodium chloride, sodium citrate, citric acid monohydrate, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

What Ondansetron Kabi looks like and contents of the pack
Ondansetron Kabi is a clear and colourless solution in plastic bottles made of LDPE.

Each bottle contains:
Ondansetron Kabi 0.08 mg/ml: 50 ml, 100 ml
Ondansetron Kabi 0.16 mg/ml: 50 ml

Pack sizes:
Ondansetron Kabi 0.08 mg/ml: 1, 10, 20, 40
Ondansetron Kabi 0.16 mg/ml: 1, 10, 20, 40

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

For UK:
Fresenius Kabi Ltd
Cestrian Court
Eastgate Way, Manor Park
Runcorn, Cheshire, WA7 1NT
United Kingdom

For IE:
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer:

Fresenius Kabi Polska Sp. z o.o.s
Henryka Sienkiewicza 25 STr.
99-300 Kutno
Poland

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	Name of the medicinal product
Belgium	Ondansetron Fresenius Kabi 0,08 mg/ml oplossing voor infusie/ solution pour perfusion/ Infusionslösung
	Ondansetron Fresenius Kabi 0,16 mg/ml oplossing voor infusie/ solution pour perfusion/ Infusionslösung
Czech Republic	Ondansetron Kabi
Germany	Ondansetron Kabi 0,08 mg/ml Infusionslösung
	Ondansetron Kabi 0,16 mg/ml Infusionslösung
Denmark	Ondansetron Fresenius Kabi
Finland	Ondansetron Fresenius Kabi 0,08 mg/ml infuusioneste, liuos
	Ondansetron Fresenius Kabi 0,16 mg/ml infuusioneste, liuos
Greece	Ondansetron/Kabi
Hungary	Ondansetron Kabi 0,08 mg/ml oldatos infúzió
	Ondansetron Kabi 0,16 mg/ml oldatos infúzió
Ireland	Ondansetron Kabi 0.08mg/ml solution for infusion
	Ondansetron Kabi 0.16mg/ml solution for infusion
Italy	Ondansetron Kabi
Netherlands	Ondansetron Fresenius Kabi 0,08 mg/ml oplossing voor infusie
	Ondansetron Fresenius Kabi 0,16 mg/ml oplossing voor infusie
Norway	Ondansetron Fresenius Kabi
Poland	Ondansetron Kabi
Spain	Ondansetrón Kabi 0,08 mg/ml solución para perfusion
	Ondansetrón Kabi 0,16 mg/ml solución para perfusión
Sweden	Ondansetron Fresenius Kabi 0,08 mg/ml
	Ondansetron Fresenius Kabi 0,16 mg/ml
Slovakia	Ondansetron Kabi 0,08 mg/ml
	Ondansetron Kabi 0,16 mg/ml
United Kingdom (Northern Ireland)	Ondansetron Kabi 0.08mg/ml solution for infusion
	Ondansetron Kabi 0.16mg/ml solution for infusion

This leaflet was last revised in March 2022.

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

Instructions for use, handling and disposal:

Keep the bottles in the outer carton in order to protect from light.
Use only clear and colourless solutions.

For single use only.
This medicinal product should be used immediately after first opening.
Any unused solution and the bottle should be adequately disposed of, in accordance with local requirements.

Compatibility with other medicinal products:

The following drugs may be administered simultaneously with Ondansetron Kabi via the Y-site of the ondansetron giving set. In general compatibility has been shown for up to 1 hour, however the recommendations listed by the manufacturer for the drug to be administered simultaneously need to be taken into account.

Cisplatin: Concentrations up to 0.48 mg/ml (e.g. 240 mg in 500 ml).

5-Fluorouracil: Concentrations up to 0.8 mg/ml (400 mg in 500 ml) administered at a rate of at least 20 ml per hour (500 ml per 24 hours). Higher concentrations of 5-fluorouracil may cause precipitation of ondansetron. The 5-fluorouracil infusion may contain up to 0.045% w/v magnesium chloride in addition to other excipients shown to be compatible.

Carboplatin: Concentrations up to 10 mg/ml (e.g. 1000 mg in 100 ml).

Etoposide: Concentrations up to 0.25 mg/ml (e.g. 250 mg in 1 litre).

Ceftazidime: Compatibility has been shown for 2000 mg reconstituted with 20 ml NaCl 0.9% (100 mg/ml) and 2000 mg reconstituted with 10 ml Water for Injections (200 mg/ml).

Cyclophosphamide: Compatibility has been shown for 1000 mg reconstituted with 50 ml NaCl 0.9% (20 mg/ml).

Doxorubicin: Concentrations of up to 2 mg/ml (e.g. 100 mg in 50 ml).

Dexamethasone: Compatibility between dexamethasone sodium phosphate in concentrations of up to 4 mg/ml and ondansetron has been demonstrated supporting administration of these drugs through the same giving set.

For complete information on this medicinal product please refer to the Summary of Product Characteristics.