PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Ondansetron Kabi 2 mg/ml solution for injection
ondansetron

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, 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 OndansetronKabi is and what it is used for

Ondansetron Kabi belongs to a group of medicines called anti-emetics, drugs 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 do you need to know before you use Ondansetron Kabi

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

Warnings and precautions
Talk to your doctor, nurse or pharmacist before using Ondansetron Kabi
- if you have reacted hypersensitive 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. Ondansetron can impede the mobility of the lower gut.
- if you have any hepatic impairment.

- 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, incl. an uneven heartbeat (arrhytmias). Ondansetron 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 drugs (e.g. 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 (drugs that slow heart rate such as atenolol or timolol): use of ondansetron with other QT prolonging drugs may result in an additional QT prolongation, i.e. increase the risk of arrhythmias.
If you are taking other serotonergic drugs 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 (e.g. hypervigilance and agitation, increased heart rate and blood pressure, tremor and overresponsive reflexes) following the concomitant use of ondansetron with other serotonergic drugs.
If you are taking apomorphine (drug 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 drugs are concomitantly administered.

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.
Ask your doctor for advice before taking any medicine.

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

Ondansetron Kabi contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium- free'.

3. How to use Ondansetron Kabi

Method of administration
Ondansetron Kabi is administered as intravenous injection (into a vein) or, after dilution, as intravenous infusion (for a longer time). 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), on your liver function and on whether it is given by injection or infusion.

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.

Children aged ≥ 6 months and adolescents
In case of chemotherapy the usual dose is a single intravenous dose of 5 mg/m^2 (body area) immediately before chemotherapy. The intravenous dose must not exceed 8 mg.

Children aged ≥1 month and adolescents
For treatment of post-operative nausea and vomiting the usual dose is of 0.1 mg/kg (body weight). The maximum dose is 4 mg as an injection into a vein.
For prevention of post-operative nausea and vomiting the usual dose is of 0.1 mg/kg (body weight). The maximum dose is 4 mg as an injection into a vein. This will be given just before the operation.

Dosage adjustment
Older people:
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 hepatic problems the dose has to be adjusted to a maximum daily dose of 8 mg ondansetron.

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.

4. Possible side effects

Like all medicines, Ondansetron Kabi 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, slow or uneven heartbeat

Rare: may affect up to 1 in 1,000 people:
- Immediate allergic reactions like 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 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

Additional side effects in children and adolescents
The side effects observed in children and adolescents were comparable to that seen in adults.

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:
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 ampoule label and carton. The expiry date refers to the last day of that month.

Keep the ampoules 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.

Each ampoule with 2 ml contains 4 mg ondansetron.
Each ampoule with 4 ml contains 8 mg ondansetron.

Each milliliter contains 2 mg ondansetron as ondansetron hydrochloride dihydrate.

The other ingredients are sodium chloride, sodium citrate dihydrate, citric acid monohydrate and water for injections.

What Ondansetron Kabi looks like and contents of the pack

Ondansetron Kabi is a clear and colourless solution in colourless glass ampoules containing 2 ml or 4 ml of solution for injection.

Pack sizes: 1, 5 and 10 ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:
Fresenius Kabi Deutschland GmbH
Else-Kroner-Strasse 1
61352 Bad Homburg v.d.Hohe
Germany

Manufacturer:
Labesfal Laboratorios Almiro S.A., Lagedo, 3465-157 Santiago de Besterios, Portugal.

This medicinal product is authorised in the Member States of the EEA under the following names:

BE: Ondansetron Fresenius Kabi 2 mg/ml Injektionslösung/oplossing voor injectie/solution injectable
CZ: Ondansetron Kabi
DE: Ondasetron Kabi 2 mg/ml Injektionslösung
DK: Ondansetron "Fresenius Kabi", injektionsvæske, opløsning
EL: Ondansetron/Kabi 2 mg/ml, Ενέσιμο διάλυμα
ES: Ondansetron Fresenius Kabi 2 mg/ml inyectable
FI: Ondansetron Fresenius Kabi 2 mg/ml injektioneste, liuos
HU: Ondansetron Kabi 2 mg/ml oldatos injekció
IE: Ondansetron Kabi 2 mg/ml solution for injection
IT: Ondansetron Kabi
NL: Ondansetron Kabi 2 mg/ml oplossing voor injectie
NO: Ondansetron Fresenius Kabi 2 mg/ml injeksjonsvæske, oppløsning
PL: Ondansetron Kabi 2 mg/ml, roztwór do wstrzykiwań
SE: Ondansetron Fresenius Kabi 2 mg/ml injektionsvätska, lösning
SK: ONDANSETRON KABI 2 mg/ml, injekčný roztok
UK: Ondansetron Kabi 2 mg/ml solution for injection

This leaflet was last revised January 2022.

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

A single dose greater than 16 mg must not be given due to risk of dose dependent increase of QT prolongation (see sections 4.2, 4.4, 4.8 and 5.1 of the SmPC).

Use only clear and colourless solutions.

For single use only. Any unused solution and the ampoule should be adequately disposed of, in accordance with local requirements.
To be used immediately after the ampoule is opened.

Ondansetron Kabi may be diluted with solutions for infusion containing:
Sodium chloride 9 mg/ml (0.9 % w/v) solution
Glucose 50 mg/ml (5 % w/v) solution
Mannitol 100 mg/ml (10 % w/v) solution
Ringer's lactate solution
Chemical and physical in-use stability has been demonstrated for 48 hours at 25°C with these solutions. Unless compatibility is proven, the solution for infusion should always be administered separately.

The diluted solutions should be stored protected from light.