Kalcex

Package leaflet: Information for the user

Ondansetron 2 mg/ml solution for injection/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.
- This medicine has been prescribed for you only. 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ondansetron is and what it is used for

Ondansetron contains a medicine called ondansetron. This belongs to a group of medicines called antiemetics that relieve nausea and vomiting.

Adults
Ondansetron is used for the management of nausea and vomiting caused by chemotherapy and radiotherapy, and for the prevention and treatment of nausea and vomiting after surgery.

Children and adolescents
Ondansetron is used for the management of nausea and vomiting caused by chemotherapy in children over 6 months of age and adolescents.
Ondansetron is used for the prevention and treatment of nausea and vomiting after surgery in children over 1 month of age and adolescents.

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

You should not be given Ondansetron if:
- you are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6);
- you are using apomorphine (to treat Parkinson's disease).

You will not be given Ondansetron if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions
Talk to your doctor or nurse before you are given Ondansetron if:
- you have symptoms of an allergic reaction such as itching, difficulty breathing or swelling of the face, lips, throat or tongue;
- you have ever been allergic to other medicines for nausea and vomiting (e.g. granisetron or palonosetron);
- you have heart problems; there may be a temporary change in electrocardiogram (ECG);
- you use medicines for treating heart rhythm disorders (antiarrhythmics) or medicines that lower blood pressure and the heart rate at rest (beta blockers);
- you are constipated or have a bowel disease that can lead to constipation;
- you have liver problems or take any medicines that may be harmful to the liver (hepatotoxic chemotherapy drugs). In these cases, your liver function will be monitored closely, especially in children and adolescents;
- if you have undergone a blood test to check your liver values (ondansetron can affect the results);
- you have problems with the levels of salts in your blood, such as potassium and magnesium;
- if you are going to have tonsil surgery. In this case, you need to be carefully monitored.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before having this medicine.

Other medicines and Ondansetron
Tell your doctor or nurse, if you are using, have recently used or might use any other medicines.

In particular, tell your doctor or nurse if you are using any of the following medicines:
- apomorphine (see 'You should not be given Ondansetron');
- carbamazepine or phenytoin (used to treat epilepsy);
- rifampicin (used to treat infections such as tuberculosis);
- tramadol (pain killer);
- medicines used to treat depression and/or anxiety:
  - SSRIs (selective serotonin reuptake inhibitors) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram;
  - SNRIs (serotonin noradrenaline reuptake inhibitors) including venlafaxine, duloxetine.

When given together with medicines for certain heart conditions, changes in your ECG picture may occur. Simultaneous use of medicinal products that damage the heart (e.g. anthracyclines (such as doxorubicin, daunorubicin) or trastuzumab), antibiotics (such as erythromycin), antifungals (such as ketoconazole), antiarrhythmics (such as amiodarone) and beta blockers (such as atenolol or timolol)) may increase the risk of heart rhythm disorders.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast- feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy
You should not use Ondansetron during the first trimester of pregnancy. This is because Ondansetron 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, think you are might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using Ondansetron.

Women of childbearing potential
If you are a woman of childbearing potential you may be advised to use effective contraception.

Breast feeding
Breast-feeding should be discontinued prior to treatment with ondansetron.

Fertility
Ondansetron has no effect on fertility.

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

Ondansetron contains sodium
This medicine contains 3.52 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.18% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ondansetron is given

Ondansetron will be given by a doctor or nurse as a slow injection or slow infusion into a vein or as an injection into a muscle.
Ondansetron is also available in dosage forms suitable for rectal and/or oral administration, and thus allows the dosage to be individually adjusted. However, Ondansetron is intended to be administered into a vein or muscle only.

The dose you have been prescribed will depend on the treatment you are having.

Adults

To prevent nausea and vomiting from chemotherapy or radiotherapy

- *On the day of chemotherapy or radiotherapy*

Ondansetron will be administered immediately before chemotherapy or radiation therapy. The usual adult dose is 8 mg, given by a slow injection into a vein or muscle, or by slow infusion into a vein.

- *On the following days*

After initial treatment, your doctor may prescribe you ondansetron to be taken by mouth or administered rectally. Please follow the instructions on respective package leaflet, as necessary. Always take ondansetron exactly as your doctor has told you.

If necessary, the dose can be increased up to 32 mg per day.

To prevent and treat nausea and vomiting after an operation

The usual adult dose is 4 mg given by a slow injection into a vein or muscle.

Paediatric population

To prevent nausea and vomiting from chemotherapy in children from 6 months and adolescents

In children, this medicine is given slowly into a vein (intravenously) immediately before chemotherapy (recommended dose: 5 mg/m^2 or 0.15 mg/kg). The intravenous dose must not exceed 8 mg. Oral dosing can commence 12 hours later. This treatment can be continued for up to 5 days after chemotherapy. The oral dose is calculated based on bodyweight or body surface area. The total daily dose must not exceed the adult dose of 32 mg.

To prevent and treat nausea and vomiting after an operation in children from 1 month and adolescents

In children, the dose is calculated based on bodyweight or body surface area. The total daily dose must not exceed the adult dose of 32 mg.

The dose is given as a slow intravenous injection before, during or after induction of anaesthesia.

Elderly (over 65 years)

Ondansetron is well tolerated in patients over 65 years of age.

Chemotherapy and radiotherapy induced nausea and vomiting

In patients 65 years of age or older, all intravenous doses should be diluted and infused over 15 minutes. If repeated dosing is necessary, these should be given at least 4 hours apart.

In patients 65 to 74 years of age, the initial dose of 8 mg or 16 mg. In patients over 75 years of age, the initial dose should not exceed 8 mg.

For the prevention and treatment of nausea and vomiting after surgery

There is limited experience in the elderly.

Patients with liver impairment
In patients with moderate or severe liver problems, the total daily dose should not exceed 8 mg.

Patients with kidney impairment
No dose adjustment or frequency of dosing, or route of administration are required.

If you are given more Ondansetron than you should
Your doctor or nurse will give you or your child Ondansetron injection 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.
The following symptoms may occur: visual disturbances, severe constipation, low blood pressure and a slow heartbeat.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The side effects in children and adolescents are similar to those in adults.

Severe allergic reactions. These rarely occur in people using ondansetron. The complaints include:
- Raised and itchy skin rash (hives)
- Swelling, sometimes of your face or mouth (angioedema) with difficulty breathing
- Brief loss of consciousness

Contact a doctor immediately if you experience any of these symptoms. Stop using this medicine.

Very common side effects (may affect more than 1 in 10 patients)
- Headache

Common side effects (may affect up to 1 in 10 patients)
- A feeling of warmth or flushing
- Constipation
- Flush
- Irritation at the site of injection (after injection into a vein)

Uncommon side effects (may affect up to 1 in 100 patients)
- Seizures
- Involuntary muscle movements or twitching
- Irregular or slow heartbeat
- Chest pain
- Low blood pressure
- Hiccups
- An increase in liver enzymes

Rare side effects (may affect up to 1 in 1,000 patients)
- Heart rhythm disturbances (which sometimes causes a sudden loss of consciousness)
- Dizziness
- Transient blurred vision or visual disturbances

Very rare side effects (may affect up to 1 in 10,000 patients)
- A widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis)
- Transient loss of eyesight

Not known (cannot be estimated from the available data)
- Dry mouth
- Myocardial ischemia (signs include: sudden chest pain or chest tightness)

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ondansetron

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

This medicine does not require any special temperature storage conditions.
Keep the ampoules in the outer carton in order to protect from light.

After opening ampoule
Once opened the product should be used immediately.

Shelf life after dilution
Chemical and physical in-use stability has been demonstrated for 7 days at 25 °C and 2 to 8 °C. From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

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

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 injection contains
– The active substance is ondansetron.
Each ml of solution contains ondansetron hydrochloride dihydrate equivalent to 2 mg ondansetron.
Each ampoule with 2 ml solution contains ondansetron hydrochloride dihydrate equivalent to 4 mg ondansetron.
Each ampoule with 4 ml solution contains ondansetron hydrochloride dihydrate equivalent to 8 mg ondansetron.

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

What Ondansetron injection looks like and contents of the pack
Clear, colourless solution, free from visible particles.

2 ml or 4 ml of solution filled in clear glass ampoules with one point cut.
Ampoules are packed in a liner. Liner is placed into outer carton.

Pack sizes:
5, 10 or 25 ampoules

Not all pack sizes may be marketed.

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

Latvia	Ondansetron Kalceks 2 mg/ml šķīdums injekcijām/infūzijām
Austria, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Iceland, Lithuania, Norway, Slovakia, Sweden:	Ondansetron Kalceks
Belgium	Ondansetron Kalceks 2 mg/ml, solution injectable/pour perfusion Ondansetron Kalceks 2 mg/ml, oplossing voor injectie/infusie Ondansetron Kalceks 2 mg/ml, Injektions-/Infusionslösung
Greece	ONDANSETRON/KALCEKS
Ireland, United Kingdom (Northern Ireland)	Ondansetron 2 mg/ml solution for injection/infusion
Italy	Ondansetrone Kalceks
The Netherlands	Ondansetron Kalceks 2 mg/ml, oplossing voor injectie/infusie
Poland	ONDANSETRON KALCEKS
Romania	Ondansetron Kalceks 2 mg/ml soluție injectabilă/perfuzabilă
Slovenia	Ondansetron Kalceks 2 mg/ml raztopina za injiciranje/infundiranje
Spain	Ondansetron Kalceks 2 mg/ml solución inyectable y para perfusión

This leaflet was last revised in 06/2024

Place for AS Kalceks internal code
Place for manufacturer internal code

The following information is intended for healthcare professionals only:

Please refer to the Summary of Product Characteristics (SmPC) for further details on this medicinal product.

Overdose
Symptoms and signs
There is limited experience of ondansetron overdose, but the following symptoms of intoxication can be expected in the event of an accidental overdose: visual disturbances, severe constipation, hypotension and a vasovagal episode with transient second-degree AV block. In all cases, the events resolved completely. Ondansetron prolongs the QT interval in a dose-dependent manner.

Paediatric population
Paediatric cases consistent with serotonin syndrome have been reported after inadvertent oral overdoses of ondansetron (exceeded estimated ingestion of 4 mg/kg) in infants and children aged 12 months to 2 years.

Management
There is no specific antidote to ondansetron. In cases of suspected overdose, symptomatic and supportive therapy should be given as appropriate. ECG monitoring is recommended. Further treatment should be as clinically indicated or as recommended by the national poisons centre, where available. The use of ipecacuanha to treat overdose is not recommended, as patients are unlikely to respond due to the antiemetic action of ondansetron itself.

Incompatibilities
Ondansetron solution for injection/infusion should not be administered in the same syringe or infusion sets as any other medication.
This medicinal product must not be mixed with other medicinal products except those mentioned below.

Instructions for use, disposal and other handling
For single use only.

The medicinal product should be visually inspected prior to use. The medicinal product should not be used if there are any visible signs of deterioration (e.g. particles or discoloration).

Ondansetron should not be autoclaved.

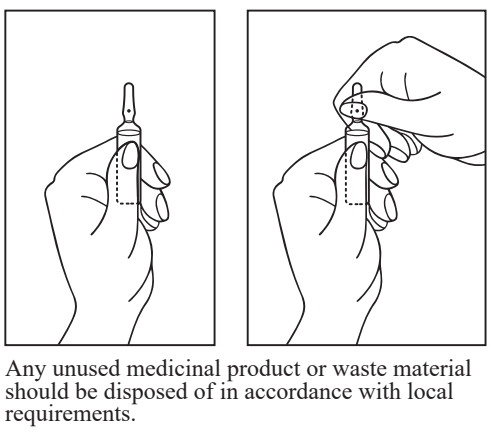
May be diluted with the following intravenous solutions for infusion:
– sodium chloride 9 mg/ml (0.9%) solution;
– glucose 50 mg/ml (5%) solution;
– mannitol 100 mg/ml (10%) solution;
– Ringer's solution;
– potassium chloride 3 mg/ml (0.3%) and sodium chloride 9 mg/ml (0.9%) solution;
– potassium chloride 3 mg/ml (0.3%) and 50 mg/ml (5%) solution;
– Lactated Ringer's solution.

Ondansetron has been shown to be compatible with polypropylene (PP) syringes, Type I glass bottles, polyethylene (PE), polyvinyl chloride (PVC) and ethyl vinyl acetate (EVA) infusion bags, and PVC and PE tubing when diluted with above mentioned solutions for infusion. Undiluted Ondansetron solution for injection/infusion has been shown to be compatible with PP syringes.

Compatibility with other drugs
Ondansetron may be administered by intravenous infusion (at 1 mg/hour). The following medicinal products may be administered via the Y-site of the ondansetron giving set for ondansetron concentrations of 16 to 160 mcg/ml (e.g. 8 mg/500 ml and 8 mg/50 ml, respectively).

– Cisplatin
– 5-Fluorouracil
– Carboplatin
– Etoposide
– Ceftazidime
– Cyclophosphamide
– Doxorubicin
– Dexamethasone

Instruction on ampoule opening
1) Turn the ampoule with coloured point up. If there is any solution in the upper part of the ampoule, gently tap with your finger to get all the solution to the lower part of the ampoule.
2) Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point (see the pictures below).



Any unused medicinal product or waste material should be disposed of in accordance with local requirements.