Package leaflet: Information for the user
Ondansetron 2 mg/ml Solution for Injection or Infusion
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 further questions, please ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of the medicinal product is Ondansetron 2mg/ml Solution for Injection or Infusion but will be referred to as Ondansetron Injection throughout the package leaflet

What is in this leaflet
1. What Ondansetron Injection is and what it is used for
2. What you need to know before you or your child use Ondansetron Injection
3. How to use Ondansetron Injection
4. Possible side effects
5. How to store Ondansetron Injection
6. Contents of the pack and other information

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

Ondansetron Injection contains the active substance ondansetron, which belongs to a group of medicines called anti-emetics. Some medical treatments can make you feel sick or vomit. Anti-emetics can prevent nausea and vomiting after your treatment.

In adults, Ondansetron is used for:
- prevent nausea and vomiting which can occur if you undergo chemotherapy (a course of chemo) or radiation (radiotherapy) during treatment for cancer
- prevent and treat nausea and vomiting which can occur after an operation under general anaesthetic.

In children aged over 1 month, Ondansetron Injection may be used to prevent and treat nausea and vomiting which can occur after an operation.

In children aged over 6 months, Ondansetron Injection may also be used for the treatment of nausea and vomiting during chemotherapy.

2. What you need to know before you or your child use Ondansetron Injection

Do not use Ondansetron Injection:
- if you or your child are using apomorphine (used to treat Parkinson's disease)
- if you or your child are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6).
- if you think that this applies to you, contact your doctor **before you are given Ondansetron Injection.**

Warnings and precautions
Talk to your doctor or pharmacist before using Ondansetron Injection
- if you or your child are **allergic** to medicines similar to ondansetron, such as medicines containing *granisetron* or *palonosetron*
- if you or your child have ever had **heart problems**, such as an **irregular heart beat** (arrhythmia)
- if you or your child have **intestinal** problems
- if your **liver** is not working well, your doctor can lower the dosage of Ondansetron injection

➔ Tell your doctor if you think that this applies to you.

Other medicines and Ondansetron Injection
Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines. This applies also to medicines obtained without a prescription.
- **phenytoin** and **carbamazepine** (medicines prescribed for epilepsy) can adversely affect the concentration of ondansetron in the body
- **rifampicin** (a medicine prescribed for pruritus, tuberculosis and leprosy) can adversely affect the concentration of ondansetron in the body
- the effect of **tramadol** (a medicine prescribed to combat pain) can be adversely affected by simultaneous use of ondansetron
- **fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram** (SSRIs) [selective serotonin reuptake inhibitors] (medicines to treat depression and/or anxiety) may cause a change in your mental state
- **venlafaxine, duloxetine** (SNRIs [serotonin-noradrenaline reuptake inhibitors]) (medicines to treat depression and/or anxiety) may cause a change in your mental state
- simultaneous use of ondansetron with medicines that affect the heart (for example anthracyclines such as **doxorubicin, daunorubicin or trastuzumab**), antibiotics (such as **erythromycin or ketoconazole**), anti-arrhythmics (such as **amiodarone**) and beta blockers (such as **atenolol or timolol**) increase the risk of heart rhythm disturbances

➔ Tell your doctor if you are using any of these medicines.

Pregnancy and breast-feeding:
You should not use Ondansetron Injection during the first trimester of pregnancy. This is because Ondansetron Injection 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 might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Ondansetron Injection. If you are a woman of childbearing potential, you may be advised to use effective contraception.

Breast –feeding is not advised during treatment with Ondansetron Injection:
Studies in animals have shown that ondansetron may be excreted in breast milk. This may affect your baby. Discuss this with your doctor.

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

Ondansetron Injection contains sodium
This medicine contains 3.62 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 to use Ondansetron injection

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Ondansetron is normally given by a nurse or doctor. The dose you have been prescribed will depend on the treatment you are having.

To prevent nausea and vomiting from chemotherapy or radiotherapy
Adults
On the day of chemotherapy or radiotherapy the recommended adult dose is 8 mg given by an injection into your vein or muscle, just before your treatment, and another 8 mg twelve hours later.
The usual adult intravenous dose does not exceed 8 mg.

On the following days
- After chemotherapy, your medicine will usually be given by mouth as an 8 mg ondansetron tablet or 10ml (8 mg) ondansetron syrup.
- oral dosing can commence twelve hours after the last intravenous dose and may be continued for up to 5 days.

If your chemotherapy or radiotherapy is likely to cause severe nausea and vomiting, you or your child may be given more than the usual dose of ondansetron. Your doctor will decide this.

To prevent nausea and vomiting from chemotherapy
Children aged over 6 months and adolescents
The doctor will decide the dose based on the child's weight or size (body surface area).

On the day of chemotherapy
- the first dose is given by an injection into the vein, just before your child's treatment. After chemotherapy, your child's medicine will usually be given by mouth as tablets or syrup.

On the following days oral dosing can commence twelve hours after the last intravenous dose and may be continued for up to 5 days.

To prevent and treat nausea and vomiting after an operation
Adults:
- The usual dose for adults is 4 mg given by an injection into your vein or an injection into your muscle. For prevention this will be given just before your operation.

Children:
- For children aged over 1 month and adolescents, the doctor will decide the dose. The maximum dose is 4 mg given as a slow injection into the vein. For prevention this will be given just before the operation.

Patients with moderate or severe liver problems
The total daily dose should not be more than 8 mg.

If you or your child keep feeling or being sick
This medicine should start to work soon after having the injection. If you or your child continue to be sick or feel sick, tell your doctor or nurse.

If you or your child have more Ondansetron injection than you should

Your doctor or nurse will give you or your child ondansetron 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.

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.

SERIOUS SIDE-EFFECTS

Allergic Reactions
If you or your child have an allergic reaction, **tell your doctor or a member of the medical staff straight away**. The signs may include:
- sudden wheezing and chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue which may make it hard to breathe
- skin rash – red spots or lumps under your skin (hives) anywhere on your body
- collapse

Contact a doctor immediately if you get these symptoms**. Stop taking this medicine.**

Other side effects include:

Very common (may affect more than 1 in 10 people)	• Headache
Common (may affect up to 1 in 10 people)	• Sensations of flushing or warmth • Constipation • Changes to liver function test results (if you have ondansetron with a medicine called cisplatin, otherwise this side effect is uncommon) • Irritation at the site of injection such as pain, burning, swelling, redness or itching

Uncommon (may affect up to 1 in 100 people)	• Seizures (fits or convulsions) • Unusual body movements or shaking (dyskinesia) • Motor disorders (including persistent muscle contraction and/or repetitive movements, dystonia) • Uneven or slow heart beat • Chest pain with and without ST segment deppression on ECG • Fixed gaze (oculogyric crisis) • Low blood pressure, which can make you feel faint or dizzy • Hiccups • Increase in substances (enzymes) produced by the liver (may show in blood tests). These symptoms have been reported commonly in patients receiving cisplatin (a drug used for chemotherapy).
Rare (may affect up to 1 in 1,000 people)	• Severe allergic reactions • Feeling dizzy or light headed during rapid administration in a vein • Transient visual disturbances (such as blurred or double vision) mainly during i.v. administration • Disturbance in heart rhythm (sometimes causing a sudden loss of consciousness) • Diarrhoea and abdominal pain
Very rare (may affect up to 1 in 10,000 people)	• Severe, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis; Lyell's syndrome) and severe allergic reaction with high fever, skin blisters, joint pain and/or eye inflammation (Stevens-Johnson syndrome) • Poor vision or temporary loss of eyesight, which usually comes back within 20 minutes. Most patients had received chemotherapeutic agents, including cisplatin. In some cases, the transient blindness has been reported to be caused by a problem in the brain.
Not known (frequency cannot be estimated from the available date)	• fluid retention (oedema) • rash and itching • Myocardial ischemia, Signs include:sudden chest pain or chest tightness

Reporting of side effects
If you or your child 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 Injection

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 or carton after EXP. The expiry date refers to last day of that month.
This medicinal product does not require any special temperature storage conditions.
Keep ampoules in the outer carton in order to protect from light

Do not use this medicine if you notice container is damaged or particles / crystals are visible.
Do not throw away any medicine 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 ingredient in Ondansetron Injection is ondansetron (as hydrochloride dihydrate).
Each ml of solution for injection or infusion contains 2 mg ondansetron (as ondansetron hydrochloride dihydrate)
Each ampoule of 2ml contains 4mg of ondansetron (as ondansetron hydrochloride dihydrate).
Each ampoule of 4ml contains 8mg of ondansetron (as ondansetron hydrochloride dihydrate).
The other ingredients are citric acid monohydrate, sodium citrate, sodium chloride, sodium hydroxide and/or hydrochloric acid for pH adjustment and water for Injections

What Ondansetron solution for Injection or Infusion looks like and contents of the pack:
Ondansetron Injection is a clear colourless solution for injection or infusion filled in clear/amber glass ampoule.
Ondansetron Injection 2 mg/ml is available in pack containing 5 X 2 ml and 5 X 4 ml ampoules and also available in 10 X 2 ml and 10 X 4 ml ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer:

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare Single Member S.A.
64th Km National Road Athens, Lamia, Schimatari 32009, Greece

This medicinal product 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
United Kingdom (Northern Ireland)	Ondansetron 2mg/ml Solution for Injection or Infusion
Austria	Ondansetron Accord 2 mg/ml Lösung zur Injektion oder Infusion
Belgium	Ondansetron Accord Healthcare 2 mg/ml solution pour injection ou perfusion/ oplossing voor injectie of infusie/ Lösung zur Injektion oder Infusion
Cyprus	Ondansetron Accord 2 mg/ml ενέσιμο διάλυμα ή διάλυμα για έγχυση

Czech Republic	Ondansetron Accord 2 mg/ml injekční roztok nebo infuzi
Denmark	Ondansetron Accord 2 mg/ml injektions og infusionsvæske, opløsning
Germany	Ondansetron Accord 2 mg/ml Injektion-/ Infusionslösung
Estonia	Ondansetron Accord 2 mg/ml
Greece	Ondansetron Accord 2 mg/ml ενέσιμο διάλυμα ή διάλυμα για έγχυση
Spain	Ondansetron Accord Healthcare 2 mg/ml para inyección o infusión EFG
Finland	Ondansetron Accord 2 mg/ ml injektio- tai infuusioneste/ Lösning för injektion och infusion
Ireland	Ondansetron 2 mg/ml Solution for Injection or Infusion
Italy	Ondansetrone Accord Healthcare 2mg/ml Soluzione per Iniezione o Infusione
Latvia	Ondansetron Accord 2 mg/ml šķīdums injekcijām vai infūzijām
Malta	Ondansetron 2 mg/ml Solution for Injection or Infusion
Norway	Ondansetron Accord 2 mg/ml oppløsning til injeksjon og infusjon
Poland	Ondansetron Accord 2 mg/ml
Portugal	Ondansetrom Accord
Sweden	Ondansetron Accord 2 mg/ml Lösning för injektion och infusion
Slovenia	Ondansetron Accord 2 mg/ml raztopina za injiciranje ali infundiranje
Slovak Republic	Ondansetron Accord 2 mg/ml injekčný alebo infúzny roztok
Bulgaria	Ondansetron Accord 2 mg/ml Solution for Injection or Infusion
The Netherlands	Ondansetron Accord 2 mg/ml oplossing voor injectie of infusie
Lithuania	Ondansetron Accord 2 mg/ml injekcinis/infuzinis tirpalas

The leaflet was last revised in January 2025

The following information is intended for medical or healthcare professionals only

Instructions for use:
For intravenous injection or intramuscular injection or intravenous infusion after dilution.
Prescribers intending to use ondansetron in the prevention of delayed nausea and vomiting associated with chemotherapy or radiotherapy in adults, adolescents or children should take into consideration current practice and appropriate guidelines.

Chemotherapy and radiotherapy induced nausea and vomiting:
Adults: The emetogenic potential of cancer treatment varies according to the doses and combinations of chemotherapy and radiotherapy regimens used. The route of administration and dose of ondansetron should be flexible in the range of 8-32 mg a day and selected as shown below.

Emetogenic chemotherapy and radiotherapy:
Ondansetron can be given either by rectal, oral (tablets or syrup), intravenous or intramuscular administration. For most patients receiving emetogenic chemotherapy or radiotherapy, ondansetron 8 mg should be administered as a slow intravenous injection (in not less than 30 seconds) or intramuscular injection, immediately before treatment followed by 8 mg orally twelve hourly.

To protect against delayed or prolonged emesis after the first 24 hours, oral or rectal treatment with ondansetron should be continued for up to 5 days after a course of treatment.
Highly emetogenic chemotherapy: For patients receiving highly emetogenic chemotherapy, e.g. high-dose cisplatin, ondansetron can be given either by oral, rectal, intravenous or intramuscular administration. Ondansetron has been shown to be equally effective in the following dose schedules over the first 24 hours of chemotherapy:

- A single dose of 8 mg by slow intravenous injection (in not less than 30 seconds) or intramuscular injection immediately before chemotherapy.
- A dose of 8 mg by slow intravenous injection (in not less than 30 seconds) or intramuscular doses of 8 mg two to four hours apart, or by a constant infusion of 1 mg/hour for up to 24 hours.
- A maximum initial intravenous dose of 16 mg diluted in 50-100 ml of saline or other compatible infusion fluid (see section 6.6) and infused over not less than 15 minutes immediately before chemotherapy. The initial dose of ondansetron may be followed by two additional 8 mg intravenous doses (in not less than 30 seconds) or intramuscular doses four hours apart.
- The selection of dose regimen should be determined by the severity of the emetogenic challenge.

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

The efficacy of ondansetron in highly emetogenic chemotherapy may be enhanced by the addition of a single intravenous dose of dexamethasone sodium phosphate, 20 mg administered prior to chemotherapy.

To protect against delayed or prolonged emesis after the first 24 hours, oral or rectal treatment with ondansetron should be continued for up to 5 days after a course of treatment.

Paediatric Population:
CINV in children aged ≥ 6 months and adolescents
The dose for CINV can be calculated based on body surface area (BSA) or weight – see below.

Dosing by BSA:
Ondansetron injection should be administered immediately before chemotherapy as a single intravenous dose of 5 mg/m^2. The single intravenous dose must not exceed 8 mg. Oral dosing can commence twelve hours later

and may be continued for up to 5 days (see SPC for dosing tables). The total dose over 24 hours (given as divided doses) must not exceed adult dose of 32 mg.

Dosing by bodyweight:
Weight-based dosing results in higher total daily doses compared to BSA-based dosing. Ondansetron injection should be administered immediately before chemotherapy as a single intravenous dose of 0.15 mg/kg. The single intravenous dose must not exceed 8 mg. Two further intravenous doses may be given in 4-hourly intervals. Oral dosing can commence 12 hours later and may be continued for up to 5 days (see SPC for further details).

Ondansetron injection should be diluted in 5% dextrose or 0.9% sodium chloride or other compatible infusion fluid (see section 6.6) and infused intravenously over not less than 15 minutes.
There are no data from controlled clinical trials on the use of Ondansetron injection in the prevention of delayed or prolonged CINV. There are no data from controlled clinical trials on the use of Ondansetron injection for radiotherapy-induced nausea and vomiting in children.

Post-operative nausea and vomiting (PONV):
Adults: For the prevention of PONV ondansetron can be administered orally or by intravenous or intramuscular injection.

Ondansetron may be administered as a single dose of 4 mg given by intramuscular or slow intravenous injection at induction of anaesthesia.

For treatment of established PONV a single dose of 4 mg given by intramuscular or slow intravenous injection is recommended.

Children (aged over 1 month and adolescents)

Oral formulation:
No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting; slow i.v. injection is recommended for this purpose.

Injection:
For prevention of PONV in paediatric patients having surgery performed under general anaesthesia, a single dose of ondansetron may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg either prior to, at or after induction of anaesthesia. For the treatment of PONV after surgery in paediatric patients, having surgery performed under general anaesthesia, a single dose of ondansetron may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg. There are no data on the use of Ondansetron in the treatment of PONV in children below 2 years of age.

Elderly: There is limited experience in the use of ondansetron in the prevention and treatment of PONV in the elderly, however ondansetron is well tolerated in patients over 65 years receiving chemotherapy.

Patients with renal impairment: No alteration of daily dosage or frequency of dosing, or route of administration is required.

Patients with hepatic impairment: Clearance of ondansetron is significantly reduced and serum half life significantly prolonged in subjects with moderate or severe impairment of hepatic function. In such patients a total daily dose of 8 mg should not be exceeded and therefore parental or oral administration is recommended.

Patients with poor sparteine/debrisoquine metabolism: The elimination half-life of ondansetron is not altered in subjects classified as poor metabolisers of sparteine and debrisoquine. Consequently, in such patients repeat

dosing will give drug exposure levels no different from those of the general population. No alteration of daily dosage or frequency of dosing is required.

Incompatibilities:
The solution must not be sterilised in an autoclave.

Ondansetron injection should only be admixed with those infusion solutions, which are recommended:
Sodium Chloride Intravenous Infusion BP 0.9%w/v
Glucose Intravenous Infusion BP 5%w/v
Mannitol Intravenous Infusion BP 10%w/v
Ringers Intravenous Infusion
Potassium Chloride 0.3%w/v and Sodium Chloride 0.9%w/v Intravenous Infusion BP
Potassium Chloride 0.3%w/v and Glucose 5%w/v Intravenous Infusion BP

The stability of Ondansetron injection after dilution with the recommended infusion fluids have been demonstrated in concentrations 0.016 mg/ml and 0.64 mg/ml.

Use only clear and colourless solutions.
The diluted solutions should be stored protected from light.

Shelf-life and storage

Unopened
3 years
This medicinal product does not require any special temperature storage conditions.
Keep ampoules in the outer carton in order to protect from light.

Injection
After first opening the medicinal product should be used immediately.

Infusion
After dilution with recommended diluents chemical and physical in-use stability has been demonstrated for 7 days at 25°C and 2-8°C.

From a microbiological point of view, the 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.