PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Ondansetron 2 mg/ml solution for injection/infusion

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 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.

The name of the medicinal product is Ondansetron 2 mg/ml solution for injection/infusion but will be referred to as Ondansetron 2 mg/ml throughout the leaflet

What is in this leaflet

1. WHAT ONDANSETRON 2 MG/ML IS AND WHAT IT IS USED FOR

Ondansetron 2 mg/ml 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 or be sick. Also after surgical treatment you can feel sick or be sick. Ondansetron 2 mg/ml may help to reduce these effects.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ONDANSETRON 2 MG/ML

Do not use Ondansetron 2 mg/ml if you:
- are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6) or to medicinal products from the same class (e.g. granisetron or dolasetron).
- are taking apomorphine (a medicine used to treat Parkinson's disease).

If you are not sure, talk to your doctor, nurse or pharmacist.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Ondansetron 2 mg/ml if:
- you are hypersensitive to other medicines against feeling sick or being sick.
- you have a blockage in your gut or have severe constipation. Ondansetron can enhance the blockage or constipation.
- you have heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles).
- you have an uneven heart beat (arrhythmias).
- you are having your tonsils out.
- your liver is not working as well as it should.
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before having Ondansetron 2 mg/ml.

Other medicines and Ondansetron 2 mg/ml

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines:
- phenytoin or carbamazepine used to treat epilepsy
- rifampicin used to treat infections such as tuberculosis (TB)
- tramadol, a pain killer
- antibiotics such as erythromycin or ketoconazole,
- anti-arrhythmic medicines used to treat an uneven heart beat,
- beta-blocker used to treat certain heart or eye problems, anxiety or prevent migraines
- medicines that affect the heart (such as haloperidol or methadone),
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram,
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine,
- anthracyclines and trastuzumab (cancer medicine)

Ondansetron changes the effect of some drugs and vice versa. This includes:
- apomorphine (a medicine used to treat Parkinson's disease): a significant drop in blood pressure and loss of consciousness has been reported with concomitant use of ondansetron and apomorphine.
- tramadol (a painkiller): ondansetron may reduce the analgesic effect of tramadol.
- phenytoin, carbamazepine (anti-epileptics) and rifampicin (an antibiotic): the blood concentrations of ondansetron are decreased.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having Ondansetron 2mg/ml.

Ondansetron 2 mg/ml should not be given in the same syringe or infusion (drip) as any other medication.

Pregnancy and breast-feeding

Only use Ondansetron 2 mg/ml during the first trimester of pregnancy after discussion with your doctor of the potential benefits and risks to you and your unborn baby of the different treatment options. This is because Ondansetron 2 mg/ml 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 pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking 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 or negligible effect on the ability to drive or use machines.

Ondansetron 2 mg/ml contains sodium

This medicine contains 3.3 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to approximately 0.17% of the recommended daily dietary intake of sodium for an adult.

3. HOW TO USE ONDANSETRON 2 MG/ML

Method of administration

Ondansetron 2 mg/ml is given as intravenous injection (into a vein) or, as intramuscular injection (into a muscle) or, after dilution, as intravenous infusion (for a longer time). It will usually be given by a doctor or a nurse. The dose you have been prescribed will depend on the treatment you are having.

Dosage

<u>To prevent nausea and vomiting from chemotherapy or radiotherapy in adults</u>

On the day of chemotherapy or radiotherapy
- the usual adult dose is 8 mg given by a slow injection into your vein or muscle, just before your treatment, and another 8 mg twelve hours later. After chemotherapy, your medicine will usually be given by mouth as 8 mg tablet or syrup.

On the following days
- the usual adult dose is 8 mg tablet or syrup taken twice a day
- this may be given for up to 5 days.

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

<u>To prevent nausea and vomiting from chemotherapy in children aged over 6 months and adolescents</u>

The doctor will decide the dose depending on the child's size (body surface area) or weight.

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 twelve hours later, as syrup or tablet.

On the following days
- 2 mg syrup twice a day for small children and those weighing 10 kg or less
- 4 mg tablet or syrup twice a day for larger children and those weighing more than 10 kg
- 8 mg tablet or syrup twice a day for teenagers (or those with a large body surface area)
- these doses can be given for up to five days

The following information is intended for healthcare professionals only:

PREPARATION GUIDE FOR:

Ondansetron 2 mg/ml solution for injection/infusion

It is important that you read the entire contents of this guide prior to the preparation of this medicinal product.

Therapeutic indications

Adults:

Ondansetron is indicated for the prevention and treatment of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, and for the prevention and treatment of post-operative nausea and vomiting (PONV).

Paediatric Population:

Ondansetron is indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children aged ≥6 months, and for the prevention and treatment of PONV in children aged ≥1 month.

For full prescribing information please consult the Summary of Product Characteristics (SmPC).

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.

Administration

Ondansetron is administered by intravenous or intramuscular injection or by intravenous infusion after dilution.

Incompatibilities

This medicinal product must not be mixed with other medicinal products except those detailed below (see Dilution).

To prevent and treat nausea and vomiting after an operation

Adult:

- The usual dose for adults is 4 mg given by a slow 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.

Dosage adjustment

Patients with moderate or severe liver problems:

The total daily dose should not be more than 8 mg.

If you keep feeling or being sick

Ondansetron 2 mg/ml should start to work soon after having the injection. If you continue to be sick or feel sick, tell your doctor or nurse.

If you use more Ondansetron 2 mg/ml than you should

Your doctor or nurse will give you or your child Ondansetron 2 mg/ml 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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Some side effects could be serious

Stop taking Ondansetron 2 mg/ml and seek medical help immediately if you or your child experience any of the following:

Allergic reactions

- sudden wheezing and chest pain or chest tightness.
- swelling of your eyelids, face, lips, mouth or tongue.
- skin rash - red spots or lumps under your skin (hives) anywhere on your body.
- collapse.

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):

- a feeling of warmth or flushing.
- constipation.
- irritation and redness at the site of injection.

Uncommon (may affect up to 1 in 100 people):

- unusual body movements or shaking.
- fits.
- chest pain, cardiac arrhythmias (changes in the way your heart beats) and bradycardia (slow heart rate). Chest pain and cardiac arrhythmias may be fatal in individual cases.
- low blood pressure, which can make you feel faint or dizzy.
- hiccups.
- asymptomatic increases of liver function. These reactions were particularly observed in patients under chemotherapy with cisplatin.
- hypersensitivity reactions around the injection site (e.g. rash, urticaria, itching) may occur, sometimes extending along the drug administration vein.

Rare (may affect up to 1 in 1,000 people):

- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness). QTc prolongation (including Torsades de Pointes)
- feeling dizzy or light headed.
- blurred vision.

Very rare (may affect up to 1 in 10,000 people):

- depression.
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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 the 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 2 MG/ML

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 2 mg/ml contains

The active substance is ondansetron.

Each ampoule with 2 ml contains 4 mg ondansetron as ondansetron hydrochloride dihydrate.

Each ampoule with 4 ml contains 8 mg ondansetron as ondansetron hydrochloride dihydrate.

Each millilitre 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 2 mg/ml looks like and contents of the pack

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

Pack sizes: 5 and 10 ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

hameln pharma ltd,
Nexus, Gloucester Business Park
Gloucester, GL3 4AG, United Kingdom

Manufacturer:

Siegfried Hameln GmbH,
Langes Feld 13, 31789 Hameln, Germany

hameln rds s.r.o.,
Horná 36, 900 01 Modra, Slovak Republic

HBM Pharma s.r.o,
Sklabinská 30, 03680 Martin, Slovak Republic

This leaflet was last revised in 01/2025

509277/06/25

Shelf life

Injection:

After first opening the medicinal product should be used immediately.

Infusion:

Chemical and physical in-use stability has been demonstrated for 48 hours at 25°C with the solutions detailed below (see Dilution).

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.

The diluted solutions should be stored protected from light.

The solution is to be visually inspected prior to use. Only clear solution practically free from particles should be used.

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

Dilution

Ondansetron 2 mg/ml may be diluted with the following solutions for infusion

- 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

The diluted solutions should be stored protected from light.

Note:

The solution for injection/infusion must not be sterilized in an autoclave!

Special precautions for storage

Keep the ampoules in the outer carton in order to protect from light.
For storage conditions of the diluted medicinal product, see above.