PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

hameln

Ondansetron 2 mg/ml Solution for Injection

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 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 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
2. What you need to know before you use Ondansetron 2 mg/ml
3. How to use Ondansetron 2 mg/ml
4. Possible side effects
5. How to store Ondansetron 2 mg/ml
6. Contents of the pack and other information

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 (hypersensitive) to ondansetron, any of the other ingredients of Ondansetron 2 mg/ml or to medicinal products from the same class (e.g. granisetron or dolasetron).
- if you are taking apomorphine (a medicine used to treat Parkinson's disease).

Warnings and precautions

Talk to your doctor or pharmacist before using Ondansetron 2 mg/ml
- if you are hypersensitive to other medicines against feeling sick or being sick.
- if you have a blockage in your gut or suffer from severe constipation. Ondansetron can enhance the blockage or constipation.
- if you have cardiac problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles).
- you have an uneven heart beat (arrhythmias).
- if you are having your tonsils out.
- if 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.

Other medicines and Ondansetron 2 mg/ml

Tell your doctor 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,
- anthracylines (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.

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 already pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Ondansetron 2 mg/ml.

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 less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. HOW TO USE ONDANSETRON 2 MG/ML

Method of administration

Ondansetron 2 mg/ml is given 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

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

Use in children and adolescents

Children aged over 6 months and adolescents

The doctor will decide the dose. In cases of chemotherapy or radiotherapy the usual dose in children and adolescents is 4 mg.

Children aged over 1 month and adolescents

The doctor will decide the dose. For treatment of post-operative nausea and vomiting a maximum dose of 4 mg is given into a vein.

Dosage adjustment

Patients with hepatic impairment:

In patients having hepatic problems the dose has to be adjusted to a maximum daily dose of 8 mg ondansetron.

Elderly:

There is limited experience in the use of ondansetron in the prevention and treatment of post-operative nausea and vomiting (PONV) in the elderly, however ondansetron is well tolerated in patients over 65 years receiving chemotherapy.

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 2 mg/ml the therapy may be continued with other dosage forms.

The following information is intended for healthcare professionals only:

PREPARATION GUIDE FOR:

hameln

Ondansetron 2 mg/ml Solution for Injection

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

Therapeutic indications

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 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).

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

Little is known at present about overdosage with ondansetron. In a few patients, the following effects were observed after overdose: visual disturbances, severe constipation, low blood pressure and unconsciousness. In all cases, the symptoms disappeared completely.

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.

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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

- 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.

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

- Immediate allergic (hypersensitivity) reactions (reaction in which the body reacts with an exaggerated immune response to a foreign agent), including life-threatening allergic reaction. These reactions may be: swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing. Additionally rash or itching and hives.

  Altered hypersensitivity reactions were also observed in patients, who were sensitive to medicinal products from the same class.

Inform your doctor immediately if you experience any symptoms suggestive of an allergic reaction.

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.
- Ondansetron is known to increase the large bowel transit time and may cause constipation in some patients.
- Local reactions at the IV injection site.

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

- Involuntary movement disorders, e.g. spasmodic movement of eyeballs, abnormal muscle contractions that may cause twisting or jerking movements of the body, seizures (e.g. epileptic spasms).
- Hypotension (low blood pressure).
- 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):

- Transitory changes in the electrocardiogram (ECG) predominantly after intravenous application of ondansetron. QTc prolongation (including Torsades de Pointes)
- Dizziness during rapid intravenous administration.
- Transient visual disturbances (e.g. blurred vision) during rapid intravenous administration.

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

- Depression.
- In individual cases transitory blindness was reported in patients receiving chemotherapeutic agents including cisplatin. Most reported cases resolved within 20 minutes. Some cases of transient blindness were reported as cortical in origin. If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Not known (cannot be estimated from the available data):

- 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 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.

Each ampoule with 4 ml contains 8 mg ondansetron.

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

Germany	Ondansetron-hameln 2 mg/ml Injektionslösung
Denmark	Ondansetron Hameln 2 mg/ml injektionsvæske, opløsning
Finland	Ondansetron Hameln 2 mg/ml injektioneste, liuos
The Netherlands	Ondansetron-hameln 2 mg/ml, oplossing voor injectie
Norway	Ondansetron Hameln 2 mg/ml injeksjonsvæske, oppløsning
Sweden	Ondansetron Hameln 2 mg/ml injektionsvätska, lösning
United Kingdom	Ondansetron 2 mg/ml Solution for Injection

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Shelf life

Unopened:

3 years

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 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.