

## Ondansetron 2 mg/ml Solution for Injection

**Read all of this leaflet carefully before this medicine is given to 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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.

**In this leaflet:**

1. What Ondansetron 2 mg/ml is and what it is used for
2. Before Ondansetron 2 mg/ml is given to you
3. How Ondansetron 2 mg/ml is given
4. Possible side effects
5. How to store Ondansetron 2 mg/ml
6. Further 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. BEFORE ONDANSETRON 2 MG/ML IS GIVEN TO YOU**

**Ondansetron 2 mg/ml must not be given (please tell your doctor)**

- 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).

**Take special care with Ondansetron 2 mg/ml and tell your doctor**

- 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.
- if you are having your tonsils out.
- if your liver is not working as well as it should.

**Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, such as phenytoin, carbamazepine, rifampicin or tramadol, anthracyclines (cancer medicine) including medicines obtained without a prescription.

If you are taking tramadol (a painkiller): ondansetron may reduce the analgesic effect of tramadol.

If you are taking phenytoin, carbamazepine (anti-epileptics) or rifampicin (an antibiotic): the blood concentrations of ondansetron are decreased.

**Pregnancy and breast-feeding**

Because of insufficient experience the use of ondansetron during pregnancy is not recommended. Ondansetron passes into mother's milk. Therefore mothers receiving ondansetron should NOT breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Ondansetron has no or negligible effect on the ability to drive or use machines.

**Important information about some of the ingredients of Ondansetron 2 mg/ml**

This medicinal product contains 2.3 mmol (53.5 mg) sodium per maximum daily dose of 32 mg. To be taken into consideration by patients on a controlled sodium diet.

**3. HOW ONDANSETRON 2 MG/ML IS GIVEN**

**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.

*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 as well as 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.

**If you received 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.

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

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Ondansetron 2 mg/ml can cause side effects, although not everybody gets them.

The frequency of side effects is classified into the following categories:

Very common	in more than 1 in 10 patients
Common	in more than 1 in 100 patients, but less than 1 in 10 patients

Uncommon	in more than 1 in 1,000 patients, but less than 1 in 100 patients
Rare	in more than 1 in 10,000 patients, but less than 1 in 1,000 patients
Very rare	in less than 1 in 10,000 patients, including isolated reports

### Serious side effects

#### Immune system disorders

Rare: 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.

#### Cardiac disorders

Uncommon: 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.

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

#### **Less serious side effects**

#### Cardiac disorders

Very rare: Transitory changes in the electrocardiogram (ECG) predominantly after intravenous application of ondansetron.

#### Nervous system disorders

Very Common: Headache.

Uncommon: 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).

Rare: Dizziness during rapid intravenous administration.

Very rare: Depression.

#### Ophthalmic disorders

Rare: Transient visual disturbances (e.g. blurred vision) during rapid intravenous administration.

Very rare: In individual cases transitory blindness was reported in patients receiving chemotherapeutic agents including cisplatin. Most reported cases resolved within 20 minutes.

#### Vascular disorders

Common: Sensations of flushing or warmth.

Uncommon: Hypotension (low blood pressure).

#### Respiratory, thorax and mediastinum disorders

Uncommon: Hiccups.

#### Gastrointestinal disorders

Common: Ondansetron is known to increase the large bowel transit time and may cause constipation in some patients.

#### Hepato-biliary disorders

Uncommon: Asymptomatic increases of liver function. These reactions were particularly observed in patients under chemotherapy with cisplatin.

#### Skin and subcutaneous tissue disorders

Uncommon: Hypersensitivity reactions around the injection site (e.g. rash, urticaria, itching) may occur, sometimes extending along the drug administration vein.

#### General disorders and administration site conditions

Common: Local reactions at the I.V. injection site.

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

### 5. HOW TO STORE ONDANSETRON 2 MG/ML

Keep out of the reach and sight of children.

Ondansetron 2 mg/ml must not be given 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. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6. FURTHER 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 plus gmbh

Langes Feld 13

31789 Hameln

Germany

*Distributor*

hameln pharmaceuticals ltd

Gloucester

United Kingdom

*Manufacturer*

hameln pharmaceuticals gmbh

Langes Feld 13

31789 Hameln

Germany

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

Germany	Ondansetron Inresa 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

**This leaflet was last approved in 08/2010.**