

## Package Leaflet: Information for the user

### Ondansetron 2 mg/ml Solution for Injection or Infusion

Ondansetron hydrochloride dihydrate

**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.

#### What is in this leaflet

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

#### 1. What Ondansetron Solution for Injection or Infusion is and what it is used for

Ondansetron is used to **prevent and treat**

- **nausea (feeling sick)** and
- **vomiting (being sick)**

caused by chemotherapy, radiotherapy or following an operation.

It belongs to a medicine group called anti-emetics.

#### 2. What you need to know before you use Ondansetron Solution for Injection or Infusion

##### Do not use Ondansetron Solution for Injection or Infusion

- if you are taking apomorphine (used to treat Parkinson's disease)
- if you are **allergic** to
  - ondansetron
  - similar ondansetron anti-emetic substances, such as granisetron or dolasetron or
  - any other ingredients of this medicine (listed in section 6).

Ask your doctor or pharmacist if you are unsure about anything before receiving Ondansetron Solution for Injection or Infusion.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Ondansetron Solution for Injection or Infusion if

- you suffer from any blockage in your gut or if you have severe constipation
- you have heart problems and at the same time have to take anaesthetics
- you are taking heart medicines, such as antiarrhythmics or beta-blockers
- you are to undergo a tonsil operation in your throat
- you are pregnant or are breast-feeding (see "Pregnancy and breast-feeding" below)
- your child is being treated with medicines which are toxic to the liver, he/she should be closely monitored for damaged liver function.

Talk to your doctor about this before having this medicine.

### **Other medicines and Ondansetron Solution for Injection or Infusion**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. It is especially important to mention any or all of the following, before taking this medicine:

- **phenytoin, carbamazepine**, used to treat epilepsy or other illness
- **rifampicin**, used to treat certain infections
- **anti-arrhythmic medicines** used to treat an uneven heart beat (e.g. as amiodarone)
- **beta-blocker medicines** used to treat certain heart or eye problems, anxiety or prevent migraines (e.g. atenolol or timolol)
- **tramadol**, a strong pain killer
- **medicines with toxic effects on the heart** (e.g. anthracyclines and trastuzimab)
- **apomorphine**, used in the treatment of Parkinson's disease
- **medicines to treat depression** (e.g. citalopram, fluoxetine, venlafaxine).

### **Pregnancy and breast-feeding**

You should not use Ondansetron Solution for Injection or Infusion during the first trimester of pregnancy. This is because Ondansetron Solution for Injection or Infusion 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 or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Ondansetron Solution for Injection or Infusion.

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

Ondansetron enters the breast milk, so you should not breast-feed while you are having this medicine.

### **Driving and using machines**

Ondansetron solution for injection does not affect the ability to drive and use machines.

### **Ondansetron Solution for Injection or Infusion contains sodium**

This medicinal product contains less than 23 mg sodium per dose, i.e. essentially 'sodium-free'.

## **3. How to use Ondansetron Solution for Injection or Infusion**

This injection will usually be given to you by a doctor or nurse. They will give you the **injection into a vein or a muscle**. The medicine may also be given as an infusion.

The doctor will decide the dose according to your therapy. The recommended Ondansetron Solution for Injection or Infusion doses are given below.

The **maximum dose** is **32 mg per day** (equal to 16 ml Ondansetron Solution for Injection or Infusion).

### **For prevention and treatment of nausea and vomiting after chemotherapy or radiotherapy**

#### **• Adults**

- The recommended starting dose is 8 mg ondansetron (equal to 4 ml Ondansetron Solution for Injection or Infusion given by an injection into your vein over at least 30 seconds or muscle, just before your treatment.

If chemotherapy presents a **high risk of causing sickness** the starting dose may be followed by

- two further 8 mg injections into your vein over at least 30 seconds or muscle, 4 hours apart, or
- a constant drip infusion of 1 mg per hour for up to 24 hours.

As an alternative, you may be given a single intravenous dose of 16 mg in a drip infusion. This will be given over not less than 15 minutes just before your chemotherapy. The initial dose of ondansetron may be followed by two further 8 mg injections into your vein over at least 30 seconds or muscle 4 hours apart.

To prevent delayed or prolonged sickness, you may be given 8 mg ondansetron by tablet every 12 hours for up to 5 days following your treatment.

A single dose greater than 16 mg 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).

- **Children, aged  $\geq 6$  months to 17 years**

The doctor will decide the dose.

- On the day of chemotherapy or radiotherapy, the first dose is given by an injection into the vein (up to 8 mg), just before your child's treatment.
- After chemotherapy, your child's medicine will usually be given by mouth; the usual dose is up to 4 mg ondansetron tablet or 5 ml (4 mg) ondansetron syrup twelve hours later.
- Additionally this may be followed up to 4 mg tablet or 5 ml (4 mg) syrup, depending on the body surface area or body weight, every 12 hours and can continue for up to 5 days after your treatment.

- **Elderly**

- All intravenous doses should be diluted in 50-100 ml of saline or other compatible infusion fluid (see section 6.6 of the SPC) and infused over 15 minutes.
- **In patients 65 to 74 years of age**, the dose schedule for adults can be followed.
- **In patients 75 years of age or older**, the initial intravenous dose of ondansetron should not exceed 8 mg. The initial dose of 8 mg may be followed by two further intravenous doses of 8 mg, infused over 15 minutes and given no less than 4 hours apart.

#### **For prevention and treatment of nausea and vomiting after an operation**

- **Adults, including elderly**

The recommended dose is 4 mg (2 ml Ondansetron Solution for Injection or Infusion) as an injection into your vein or muscle. This will be given either

- when you have the anaesthetic or
- after the operation if you are sick or feel sick.

- **Children, aged  $\geq 1$  months to 17 years**

The doctor will decide the dose. The maximum dose is 4 mg (2 ml Ondansetron Solution for Injection or Infusion) given as an injection into a vein.

#### **Children younger than 2 years**

For treatment of nausea and vomiting of children younger than 2 years there is no information to date.

#### **Patients with liver problems**

The largest daily dose you will be given is 8 mg (4 ml Ondansetron Solution for Injection or Infusion), depending on the seriousness of your liver problem.

#### **If you have more Ondansetron Solution for Injection or Infusion than you should**

Your doctor or nurse will give you or your child Ondansetron Solution for Injection or Infusion 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 forget to use Ondansetron Solution for Injection or Infusion**

If you feel that you have not received your dose of ondansetron please discuss it with your doctor or nurse.

#### **If you stop using Ondansetron Solution for Injection or Infusion**

Your doctor will decide if you no longer need to receive ondansetron.

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 this medicine and seek medical help immediately if you or your child experience any of the following:

**Severe allergic reaction:**

Symptoms may include:

- a severe itchy skin rash, especially with red spots or blisters
- swelling of the hands, face, lips, mouth, or throat
- difficulty breathing.

**Myocardial ischemia**

Signs include:

- sudden chest pain or
- chest tightness.

See chapter 2 “Do not use Ondansetron Solution for Injection or Infusion”.

**Very common side effects**, may affect more than 1 in 10 people:

- headache.

**Common side effects**, may affect up to 1 to 10 people:

- constipation
- increases in liver blood test results (if you have ondansetron injection with a medicine called cisplatin, otherwise this side effect is uncommon)
- feeling flushed or warm
- allergic reactions around the injection site such as rash, nettle rash or itching.

**Uncommon side effects**, may affect up to 1 in 100 people:

- hiccups
- fits
- problems with eye-movements
- spasms in the muscles of the head and neck
- slow or irregular heartbeat
- chest pain with abnormal ECG heart tracing
- low blood pressure
- increases in liver blood test results.

**Rare side effects**, may affect up to 1 in 1000 people:

- allergic reactions
- dizziness
- blurred vision
- abnormal ECG heart tracing.

**Very rare side effects**, may affect up to 1 in 10,000 people:

- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (toxic skin eruption, including toxic epidermal necrolysis).

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Ondansetron Solution for Injection or Infusion

You will normally not be asked to store your medicine. It will usually be brought to you ready to be given straight away.

**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 label and the carton after EXP (abbreviation used for expiry date). The expiry date refers to the last day of that month.

Keep the ampoules in the outer carton.

Do not use this medicine if you notice signs of deterioration such as colouration of the solution or when particles are visible. Do not give Ondansetron Solution for Injection or Infusion in the same syringe or same drip infusion as other medicines.

Any unused solution should be discarded.

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.

Dilutions of Ondansetron Solution for Injection or Infusion in compatible infusion liquids are chemically and physically stable at room temperature or refrigerated for 28 days. In keeping with good pharmaceutical practice dilutions of Ondansetron Solution for Injection or Infusion in intravenous fluids should be prepared at infusion time or stored at 2 - 8 °C for no more than 24 hours before the administration begins.

## 6. Contents of the pack and other information

### What Ondansetron Solution for Injection or Infusion contains

- The **active substance** is **ondansetron** hydrochloride dihydrate.  
Each ml solution for injection contains 2.494 mg ondansetron hydrochloride dihydrate equivalent to 2 mg ondansetron.
- The other ingredients are citric acid monohydrate, sodium citrate, sodium chloride, water for injections.

### What Ondansetron Solution for Injection or Infusion looks like and contents of the pack

Ondansetron Solution for Injection or Infusion is a clear and colourless solution.

It is available in cartons of 1, 5 or 50 glass ampoules.

Ondansetron Solution for Injection or Infusion is available in two different sizes of ampoules.

The 2 ml ampoule contains 5 mg ondansetron hydrochloride dihydrate, equivalent to 4 mg ondansetron, in 2 ml of aqueous solution (2 mg/ml).

The 4 ml ampoule contains 10 mg ondansetron hydrochloride dihydrate, equivalent to 8 mg ondansetron, in 4 ml of aqueous solution (2 mg/ml).

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturers

#### Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

#### Manufacturers

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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

Ireland                      Ondansetron 2 mg/ml Solution for Injection or Infusion

**This leaflet was last revised in 02/2022.**