

## PACKAGE LEAFLET INFORMATION FOR THE USER

# Ondansetron 4mg/5ml Oral Solution

(ondansetron hydrochloride dihydrate)

**READ ALL THIS LEAFLET CAREFULLY BEFORE YOU START TAKING 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 your pharmacist.
- This medicine has been prescribed only 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 these side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist (see section 4).

### What is in this leaflet

1. What Ondansetron 4mg/5ml Oral Solution is and what it is used for
2. What you need to know before you take Ondansetron 4mg/5ml Oral Solution
3. How to take Ondansetron 4mg/5ml Oral Solution
4. Possible side effects
5. How to store Ondansetron 4mg/5ml Oral Solution
6. Contents of the pack and other information

### 1. What Ondansetron 4mg/5ml Oral Solution is and what it is used for

Some medical and surgical treatments can make you feel sick or be sick (nausea and vomiting). Ondansetron 4mg/5ml Oral Solution belongs to a group of medicines called anti-emetics, which can stop these effects. This medicine is used to stop nausea and vomiting after

- chemotherapy for cancer (in adults and children)
- radiotherapy for cancer (adults only)
- an operation (adults only).

**Ask your doctor, nurse or pharmacist if you would like further explanation about these uses.**

### 2. What you need to know before you take Ondansetron 4mg/5ml Oral Solution

#### Do not take Ondansetron 4mg/5ml Oral Solution if you:

- are taking **apomorphine** (used to treat Parkinson's disease)
- are **allergic** (hypersensitive) to ondansetron or any of the other ingredients in Ondansetron 4mg/5ml Oral Solution (listed in Section 6).

If you are not sure, talk to your doctor, nurse or pharmacist before taking Ondansetron 4mg/5ml Oral Solution.

### Warnings and precautions

Check with your doctor, nurse or pharmacist before taking Ondansetron 4mg/5ml Oral Solution if you:

- have ever had **heart problems** (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- an **uneven heartbeat** (arrhythmias)
- are **allergic to similar medicines**, such as granisetron (also known as "Kytrel") or palonosetron
- have **liver problems**
- have a **blockage in your gut** or you suffer from **severe constipation**
- **have a problem 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 taking this medicine.

### Taking other medicines

**Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines**, including medicines obtained without a prescription and herbal medicines. This is because ondansetron can affect the way other medicines work. Also, some other medicines can affect the way ondansetron works. In particular make sure your doctor or pharmacist knows if you or your child are taking:

- **carbamazepine** or **phenytoin** (to treat epilepsy)
- **rifampicin** (to treat serious infections such as tuberculosis (TB))
- **tramadol** (to control pain)
- medicines that affect the heart (such as **haloperidol** or **methadone**)
- medicines to treat cancer (especially **anthracyclines** or **trastuzumab**)
- **anti-arrhythmic medicines** (to treat an uneven heartbeat)
- **beta-blocker medicines** (to treat certain heart or eye problems, anxiety or prevent migraines)
- **antibiotics** such as **erythromycin** or **ketoconazole**
- **SSRIs** (selective serotonin reuptake inhibitors) used to treat depression and/anxiety including **fluoxetine**, **paroxetine**, **sertraline**, **fluvoxamine**, **citalopram**, **escitalopram**
- **SNRIs** (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including **venlafaxine**, **duloxetine**.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before using Ondansetron 4mg/5ml Oral Solution.

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

Only use Ondansetron 4mg/5ml Oral Solution 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 4mg/5ml Oral Solution can slightly increase the risk of a baby being born with a cleft lip and/or cleft palate (openings or splits in the upper lip and/or 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 4mg/5ml Oral Solution. If you are a woman of childbearing potential you may be advised to use effective contraception.

**Do not breast-feed** if you are taking Ondansetron, as small amounts can pass into the breast milk. Ask your doctor or midwife for advice.

### **Driving and using machines**

Ondansetron 4mg/5ml Oral Solution should not affect your ability to drive or to operate machinery, but if you feel faint or dizzy, do not drive or operate machinery until you feel better.

### **Important information about some of the ingredients of Ondansetron Oral Solution**

This medicine contains 392 mg sorbitol in each ml which is equivalent to 1960 mg in 5 ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicine contains 2 mg sodium benzoate in each ml which is equivalent to 10 mg in 5 ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

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

This medicine also contains 2.275 mg propylene glycol in each ml which is equivalent to 11.375 mg in 5 ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

### **3. How to take Ondansetron 4mg/5ml Oral Solution**

Always take Ondansetron 4mg/5ml Oral Solution exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure. The dose you have been prescribed will depend on the treatment you are having. Do not mix your medicine with anything (not even water) before swallowing it.

#### **To prevent nausea and vomiting from chemotherapy or radiotherapy**

On the day of chemotherapy or radiotherapy

- the usual adult dose is 8 mg taken one to two hours before treatment and another 8mg twelve hours after.

On the following days

- the usual adult dose is two 5 ml spoonfuls twice a day
- this may be given for up to 5 days

**Children aged over 6 months and adolescents:** The doctor will decide the dose depending on the child's size (body surface area) or weight. Look at the label for more information.

- the usual dose for a child is up to one 5 ml spoonful twice a day
- this can be given for up to 5 days.

#### **To prevent nausea and vomiting after an operation**

The usual adult dose is four 5ml spoonfuls before your operation.

#### **For children aged over 1 month and adolescents:**

It is recommended that Ondansetron is given as an injection.

#### **Patients with moderate to severe liver problems**

The total daily dose should not be more than 8mg (two 5 ml spoonfuls).

Ondansetron 4mg/5ml Oral Solution should start to work within 1-2 hours of taking a dose.

#### **If you are sick (vomit) a dose back within 1 hour of taking a dose**

- then take the same dose again
- otherwise do not take more doses than the label says. If you continue to be sick or feel sick, tell your doctor or nurse.

#### **If you take more than you should**

If you or your child take more than you should, talk to your doctor or go to hospital straight away. Take the medicine pack with you.

#### **If you forget to take**

If you miss a dose **and** feel sick or vomit

- take a dose as soon as possible, then
- take the next dose at the usual time (as shown on the label)
- do not take a double dose to make up for a forgotten dose.

#### **If you miss a dose but do not feel sick**

- take the next dose when due (as shown on the label)
- do not take a double dose to make up for a forgotten dose.

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

#### 4. Possible side effects

Like all medicines, Ondansetron 4mg/5ml Oral Solution can cause side effects, although not everybody gets them.

##### Allergic reactions

A few people may be allergic to Ondansetron 4mg/5ml Oral Solution, however this is rare, affecting less than 1 in 1000 patients. If you have an allergic reaction **stop taking this medicine and seek medical attention immediately**. The signs may include:

- sudden wheeziness and chest pain or chest tightness
- difficulty breathing
- swelling of eyelids, face, lips, mouth or tongue
- skin rash - red spots or red spots or lumps under your skin (hives) anywhere on your body
- feeling faint, especially when standing up
- collapse.

##### Other side effects include:

**Very common** (affects more than 1 in 10 people)

- headache.

**Common** (affects less than 1 in 10 people)

- a feeling of warmth or flushing
- constipation
- changes to liver function test results (if you take Ondansetron 4mg/5ml Oral Solution with a medicine called cisplatin, otherwise this side effect is uncommon).

**Uncommon** (affects less than 1 person in 100 people)

- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heartbeat
- chest pain
- fits
- unusual body movement or shaking

**Rare** (affects less than 1 in 1,000 people)

- feeling dizzy or light headed
- blurred vision
- disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

**Very rare** (affects less than 1 in 10,000 people)

- poor vision or temporary loss of eyesight which usually comes back within 20 minutes. This is much less likely when ondansetron is given by mouth.

##### 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](http://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 4mg/5ml Oral Solution

- Keep out of the sight and reach of children.
- Do not store above 30°C.
- **Do not refrigerate**. Keep the bottle upright.
- **Do not use after 28 days** of first opening the bottle. Do not use after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

#### 6. Contents of the pack and other information

##### What Ondansetron 4mg/5ml Oral Solution contains

- The active substance is ondansetron. Each 5 ml spoonful contains 4mg ondansetron.
- The other ingredients are sodium citrate (E331), citric acid (E330), saccharin sodium, sorbitol (E420), sodium benzoate (E221), strawberry flavour (contains propylene glycol (E1520)) and purified water.

##### What Ondansetron 4mg/5ml Oral Solution looks like and contents of the pack

Ondansetron 4mg/5ml Oral Solution is a clear, sucrose- free, strawberry flavoured solution. It is supplied in a 50ml amber glass bottle, packed in a carton with a double ended (5ml and 2.5ml) measuring spoon.

##### Marketing Authorisation Holder

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PL 14308/0015  
This leaflet was last revised in June 2021.