

Package leaflet: Information for the patient

# Ondansetron 8 mg orodispersible tablets

## Ondansetron

**Read all of 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 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 is and what it is used for
2. What you need to know before you take Ondansetron
3. How to take Ondansetron
4. Possible side effects
5. How to store Ondansetron
6. Contents of the pack and other information

### 1. What Ondansetron is and what it is used for

This medicine contains Ondansetron, which belongs to a group of medicines called anti-emetics which help to stop you feeling or being sick.

Ondansetron is used to treat nausea (feeling sick) and vomiting (being sick) caused by some medical treatments, such as chemotherapy or radiotherapy for cancer in adults. It is also used to prevent nausea and vomiting in patients following an operation.

### 2. What you need to know before you take Ondansetron

#### Do not take Ondansetron

- if you are allergic to ondansetron, benzyl alcohol, sulphites or any of the other ingredients of this medicine (listed in section 6 "Contents of the pack and other information")
- if you are taking apomorphine (a medicine used to treat Parkinson's disease).

**Do not give** the tablets to children.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Ondansetron

- if you are allergic to medicines (5-HT<sub>3</sub> antagonists) similar to ondansetron
- if you are due to have surgery to the adenoids or tonsils
- if you have heart problems including irregular heartbeat (arrhythmia)
- if you are taking certain medicines to treat depression and/or anxiety (selective serotonin reuptake inhibitors [SSRIs] such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram and escitalopram or selective noradrenaline reuptake inhibitors [SNRIs] such as venlafaxine or duloxetine) or if you are taking buprenorphine, a medicine used to treat pain. The use of these medicines together with Ondansetron can lead to serotonin syndrome, a potentially life-threatening condition. You may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- if you have digestive disorders
- if you have liver problems, in which case your doctor will possibly reduce your ondansetron dose
- if you have problems with salt levels in your blood (electrolyte disorders), e.g. potassium and magnesium.

If you think any of the above points apply to you, do not take Ondansetron until you have discussed it with your doctor.

#### Other medicines and Ondansetron

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.

Some medicines may alter the effects and/or side effects of Ondansetron or Ondansetron may alter the effects and/or side effects of some medicines. These include:

- apomorphine (a medicine used to treat Parkinson's disease), as a sharp drop in blood pressure and loss of consciousness have been reported when Ondansetron was used with apomorphine
- carbamazepine, phenytoin (medicines used to treat epilepsy)
- rifampicin (a medicine for tuberculosis)
- medicines that affect the heart, such as certain medicines for cancer (anthracyclines or trastuzumab) or medicines that prolong the QT interval (a delay in the transmission of impulses in the heart muscle, visible on the ECG, with the risk of life-threatening heart rhythm disorders)
- tramadol and buprenorphine, medicines used to treat pain (see "Warnings and precautions")
- selective serotonin reuptake inhibitors (SSRIs) used to treat depression and/or anxiety, such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram or escitalopram
- selective noradrenaline reuptake inhibitors (SNRIs) used to treat depression and/or anxiety, such as venlafaxine or duloxetine (see "Warnings and precautions").

### Pregnancy, breastfeeding and fertility

You should not use Ondansetron during the first trimester of pregnancy. This is because Ondansetron 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. If you are a woman of childbearing potential you may be advised to use effective contraception.

If you are taking Ondansetron, you should not breast-feed your baby.

### Driving and using machines

Ondansetron is unlikely to affect your ability to drive or operate machinery.

### Ondansetron tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### Ondansetron tablets contain aspartame

This medicine contains 6 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### Ondansetron tablets contain benzyl alcohol

This medicine contains up to 100 micrograms of benzyl alcohol in each tablet. Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding or if you have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis"). Benzyl alcohol may cause allergic reactions.

**Ondansetron tablets contain sulphites**, which may rarely cause severe hypersensitivity reactions and bronchospasm.

### Ondansetron tablets contain sodium

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

### 3. How to take Ondansetron

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

**To protect you from nausea and vomiting during and after cancer treatment with cytostatic agents (chemotherapy) or radiation therapy:**

#### Adults

##### On the day of chemotherapy or radiation therapy:

The usual dose is 8 mg Ondansetron, taken one to two hours before treatment, and a further 8 mg Ondansetron twelve hours later.

##### On the following days:

On the following days, you will receive Ondansetron in the form of orodispersible tablets (that dissolve in the mouth), film-coated tablets or as a solution. Always use this medicine exactly as described in this leaflet or as your doctor or nurse has told you.

The usual dose is 8 mg Ondansetron twice a day at 12 hour intervals for up to 5 days.

#### Use in children and adolescents

Ondansetron 8 mg tablets must not be used in children. For this patient group, more suitable dosage forms with a lower level of active substance are available.

#### Elderly patients

No dose adjustment or change in dosing frequency is required.

### Prevention of sickness (nausea and vomiting) after an operation:

#### Adults

Unless otherwise prescribed by the doctor, the usual dose is 16 mg Ondansetron, one hour before anaesthesia.

#### Use in children and adolescents

The tablets must not be used in children. For this patient group, more suitable dosage forms with a lower level of active substance are available.

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Farben	black
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#### Elderly patients

Experience with ondansetron in the prevention of nausea and vomiting after an operation in elderly patients is limited.

#### Patients with kidney problems

No dose adjustment is required.

#### Patients with liver problems

In patients with moderate to severely impaired liver function, the total daily dose should not be more than 8 mg.

#### Route of administration






The tablets should be taken by mouth. They will break up rapidly in the mouth and can then be swallowed. You should wash them down with a glass of water.

**Important:** Do not remove the tablets from their blister or pierce the foil until you are ready to take them.

#### Follow these instructions carefully:

Do not push the orodispersible tablet through the blister.

#### The tablet(s) must be taken as follows:

				
In order to stop the tablet from breaking, <b>do not push</b> the tablet out of its blister.	Tear along the perforations of the foil to separate one blister unit.	Remove the covering foil carefully. Start with the corner that is marked with an arrow.	Place the tablet on top of your tongue with dry hands. The tablet will dissolve very quickly, and you should then swallow it with water.	

#### If you take more Ondansetron than you should

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

#### If you forget to take Ondansetron

Do not take a double dose to make up for a forgotten dose. Take your missed dose for nausea or vomiting as quickly as possible and then continue taking your medicine as normal.

If you are unsure what to do, ask your doctor or pharmacist.

#### If you stop taking Ondansetron

Take Ondansetron for as long as your doctor recommends it. Do not stop unless advised by your doctor.

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.

#### Severe allergic reactions:

These are rare in patients taking Ondansetron. Signs of these may be:

- raised or itchy rash (hives).
- swelling, sometimes in the face or mouth (angioedema), which may cause breathing difficulties.
- collapse.

#### Myocardial ischaemia (frequency unknown):

Signs include:

- sudden chest pain or
- chest tightness

Contact your doctor or pharmacist immediately if you notice these symptoms and **stop taking Ondansetron.**

#### Other side effects

#### Very common: may affect more than 1 in 10 people

- headache.

#### Common: may affect up to 1 in 10 people

- sensation of warmth, hot flushes with skin redness.
- constipation.

#### Uncommon: may affect up to 1 in 100 people

- seizures.
- movement disorders or spasms (including extrapyramidal reactions such as muscle tone disorders, eye muscle disorders [oculogyric crisis] and motor disorders), but these were shown not to have any long-term clinical consequences.
- chest pain (with or without ST-segment depression on the ECG).
- irregular or slow heart beat (heart rhythm disorder, bradycardia).
- low blood pressure.
- hiccups.
- increase in substances (enzymes) produced by the liver (increase in liver function tests).

#### Rare: may affect up to 1 in 1,000 people

- severe allergic reactions.
- rhythm disorders (QT prolongation including torsade de pointes, which may cause a sudden loss of consciousness).
- temporary visual disturbances (e.g. blurred vision), mainly with IV administration.
- dizziness, mainly with rapid IV administration.

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

- extensive rash with blistering and skin peeling over large areas of the skin surface (toxic epidermal necrolysis)
- temporary blindness, mainly with IV administration.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [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

Keep this medicine out of the sight and reach of children. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date, which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via waste water or house hold 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 contains

- The active substance is ondansetron. Each tablet contains 8 mg of ondansetron.
- The other ingredients are mannitol (E421), crospovidone (Type A), lactose monohydrate, microcrystalline cellulose, aspartame (E951), colloidal anhydrous silica, magnesium stearate, strawberry guarana flavour (maltodextrin, propylene glycol, artificial flavours containing amongst other ingredients [benzyl alcohol, ethanol, potassium, propylene glycol, sodium, sulphites] and acetic acid).

#### What Ondansetron looks like and contents of the pack

White to off-white, round tablets indented with '7' on one side and 'E' on the other side with a raised circular edge.

The tablets are available in packs of 6, 10, 30, 50 & 100 tablets. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer:

Aristo Pharma GmbH  
Wallenroder Straße 8-10  
Berlin 13435  
Germany

**ARISTO**

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