



Package leaflet: Information for the user

Ondansetron 4 mg film-coated tablets Ondansetron 8 mg film-coated tablets

Ondansetron (as hydrochloride dihydrate)

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 further 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 and children). It is also used to prevent nausea and vomiting in patients following an operation (adults only).

2. What you need to know before you take Ondansetron

Do not take Ondansetron

- if you are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had any allergic (hypersensitive) reaction with other anti-emetics (for example granisetron or dolasetron)
- if you are taking apomorphine (used to treat Parkinson's Disease)

Warnings and precautions

Talk to your doctor or pharmacist before taking Ondansetron

- if you have a blockage in your gut or suffer from severe constipation
- if you are due to have surgery to the adenoids or tonsils
- if you have a heart problem
- if you have an uneven heart beat (arrhythmias)
- if you have liver problems
- if you have problems with the levels of salts in your blood, such as potassium and magnesium.

If any of the above apply, you should inform your doctor before beginning treatment with Ondansetron.

Other medicines and Ondansetron

Ondansetron may have an effect on other drugs and other drugs may have an effect on Ondansetron.

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

In particular it is important to tell your doctor if you are taking any of the following medicines:

- Medicines used to treat epilepsy (phenytoin, carbamazepine)
- Rifampicin (an antibiotic).
- Tramadol (a medicine used to treat pain)
- Medicines used to treat heart problems such as abnormal heart beats (anti-arrhythmics) and/or high blood pressure (beta-blockers)
- cancer medicines (especially anthracyclines) as these may interact with Ondansetron to cause heart arrhythmias
- antibiotics (such as erythromycin or ketoconazole).

Pregnancy, breast-feeding and fertility Pregnancy:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The safety of using Ondansetron during pregnancy has not been established. Therefore the use of Ondansetron is not recommended during pregnancy.

Breast-feeding:

You should not breast-feed your infant whilst taking Ondansetron. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Ondansetron contains lactose

Ondansetron contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ondansetron

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

Treatment of sickness (nausea and vomiting) in patients receiving chemotherapy or radiotherapy:

Adults (including the elderly): The usual dose is 8 mg of Ondansetron 1 to 2 hours before chemotherapy or radiotherapy, followed by 8 mg of Ondansetron 12 hours later.

To protect against delayed, or further, sickness a dose of 8 mg of Ondansetron may be continued twice a day for up to 5 days after treatment.

Infants and Children (aged 6 months and over) and adolescents (under 18 years old):

Your doctor will decide what dose of Ondansetron should be given. This will depend on the size and weight of the child.

Patients with liver problems:

The total daily dose should not be more than 8 mg.

To prevent sickness (nausea and vomiting) after an operation:

Adults: The usual dose is 16 mg before your operation **or** an 8 mg tablet one hour before the operation, then

- another 8 mg tablet eight hours after the first dose, then
- a further 8 mg tablet eight hours after the second dose

If you are sick (vomit) within one hour of taking an 8 mg dose:

- Take another 8mg tablet
- Otherwise, do not take more Ondansetron tablets than the label says.

If you take more Ondansetron than you should

If you have taken too many tablets it is important to contact your doctor as soon as possible or go to your nearest hospital casualty department immediately. Take the medicine packet with you, even if there are no tablets left, so that the doctor knows which tablets were taken.

If an overdose has been taken, symptoms may include problems with vision, low blood pressure (which could cause dizziness or faintness) or irregular heart beat.

If you or your child 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

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop using Ondansetron
Do not stop taking your tablets, even if you are feeling well, without consulting a 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.

If any of the following effects happen, **stop taking your tablets and tell your doctor immediately:**

- An **allergic** reaction. The symptoms may include:
 - Sudden wheezing and chest pain or tightness
 - Swelling of the eyelids, face, lips, mouth tongue or throat
 - Difficulty breathing
 - Collapse
 - Skin rash
- Fits (seizures)
- Chest pain
- Temporary loss of vision which usually comes back within 20 minutes

Side effects of Ondansetron

If you are concerned about any side effects please talk to your doctor. If any of the following side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Very common (may affect more than 1 in 10 people):

- Headache

Common (may affect up to 1 in 10 people):

- Sensation of flushing and warmth
- Constipation
- Local burning sensation (following insertion of suppositories).
- Local IV injection site reactions

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

- uncontrollable movements of the body, including upward rolling movement of the eyeballs
- Fits (seizures). **If this should occur seek urgent medical attention**
- Dizziness (during rapid IV administration)
- (Irregular heart beat, fast or slow heart rate)
- Chest pain. **If this should occur seek urgent medical attention.**
- Low blood pressure
- Hiccups
- An increase in liver function test results (most often in patients receiving chemotherapy with cisplatin)

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

- An immediate allergic reaction, which may be serious and include symptoms such as sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse, skin rash. **If this should occur, seek urgent medical attention.**
- Visual disturbances e.g. blurred vision (though this has almost always been associated with an Ondansetron injection rather than tablets).
- Effects on heart rhythms that can be seen on an ECG (an electrical trace of your heart). Symptoms may include feeling lightheaded or loss of consciousness.

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

- Temporary loss of vision which usually comes back within 20 minutes. **If this should occur seek urgent medical attention.** Temporary loss of vision has almost always been reported with Ondansetron injection, rather than tablets, and usually when given with chemotherapy containing cisplatin.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Malta

ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website:

www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

The United Kingdom

Yellow Card Scheme
Website:
www.mhra.gov.uk/yellowcard

5. How to store Ondansetron

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

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 wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What Ondansetron contains

- The active substance is ondansetron hydrochloride dihydrate.
4 mg: Each tablet contains 4 mg of ondansetron (as ondansetron hydrochloride dihydrate).
8mg: Each tablet contains 8 mg of ondansetron (as ondansetron hydrochloride dihydrate).
- The other ingredients are *Tablet core:* Lactose anhydrous, cellulose, microcrystalline (E460), starch, pregelatinised (maize), magnesium stearate (E572)
Film coat:
4 mg: Triacetin (E1518), titanium dioxide (E171), hypromellose (E464)
8 mg: Triacetin (E1518), titanium dioxide (E171), hypromellose (E464), iron oxide yellow (E172)

What Ondansetron looks like and contents of the pack

Film-coated tablet.

Ondansetron 4 mg film-coated tablets

White to off-white, oval shaped, film-coated tablets debossed with 'E' on one side and '01' on the other side.

Ondansetron 8 mg film-coated tablets

Yellow, oval shaped, film-coated tablets debossed with 'E' on one side and '02' on the other side.

Ondansetron 4 mg and 8 mg film-coated tablets are available in packs of 3, 4, 6, 7, 10, 14, 15, 20, 28, 30, 40, 49, 50, 60, 90, 100, 200, 300 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder

UK - Milpharm Limited
Ares Block
Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

MT - Aurobindo Pharma (Malta)
Limited Vault 14, Level 2,
Valletta Waterfront
Floriana FRN 1913
Malta

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal
Far Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares Block
Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

This leaflet was last revised in 07/2018.