



**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

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 for:
- preventing nausea and vomiting caused by chemotherapy (in adults and children) or radiotherapy for cancer (adults only)
- preventing nausea and vomiting after surgery (adults only).

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

## 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 (e.g. congestive heart failure which causes shortness of breath and swollen ankles).
- 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, sodium 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. This includes medicines that you buy without a prescription and herbal medicines. This is because Ondansetron can affect the way some medicines work. Also some other medicines can affect the way Ondansetron works.

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 (used to treat infections such as tuberculosis (TB) an antibiotic).
- Tramadol (a medicine used to treat pain)
- medicines that affect the heart (such as haloperidol or methadone)
- Medicines used to treat heart problems such as abnormal heart beats (anti-arrhythmics like amiodarone) and/or high blood pressure (beta-blockers like atenolol, timolol)
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- cancer medicines (especially anthracyclines such as doxorubicin, daunorubicin and monoclonal antibodies such as trastuzumab) as these may interact with Ondansetron to cause heart arrhythmias
- antibiotics (such as erythromycin or ketoconazole),
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.

**Pregnancy, breast-feeding and fertility**

**Pregnancy:**

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. It is recommended that sexually active women of childbearing potential use effective contraception (methods resulting in less than 1% pregnancy rate) during treatment with ondansetron.

**Breast-feeding:**

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

**Fertility**

There are no data on the effects of ondansetron on fertility in humans.

**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.

**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 8 mg twelve hours after.

On the following days
- the usual adult dose is 8 mg 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 4 mg 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 16 mg before your operation

Children aged over 1 month and adolescents:
It is recommended that this medicine is given as an injection.

**Patients with moderate or severe liver problems**

The total daily dose should not be more than 8 mg.
Ondansetron tablets should start to work within one or two hours of taking a dose.

**If you are sick (vomit) within one hour of taking a dose**
- take the same dose again
- otherwise, do not take more Ondansetron tablets than the label says.

If you continue to feel sick, tell your doctor or nurse.

**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.

**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:

**Allergic reactions**
- sudden wheezing and chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue
- skin rash – red spots or lumps under your skin (hives) anywhere on your body
- collapse

**Myocardial ischemia**
Signs include:
- sudden chest pain or
- chest tightness

**Other side effects include:**
**Very common (may affect more than 1 in 10 people)**
- headache

**Common (may affect up to 1 in 10 people)**
- a feeling of warmth or flushing
- constipation
- changes to liver function test results (if you take Ondansetron tablets with a medicine called cisplatin, otherwise this side effect is uncommon)

**Uncommon (may affect up to 1 in 100 people)**
- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heart beat
- chest pain
- fits
- unusual body movements or shaking

**Rare (may affect up to 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 (may affect up to 1 in 10,000 people)**
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes

**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 at:
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.

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. Contents of the pack and other 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, 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

**Manufacturer**
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
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or

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