

Package Leaflet: Information for the User

Ondansetron 4mg Film-coated Tablets
Ondansetron 8mg Film-coated Tablets
ondansetron

Read all of this leaflet carefully before you start to take your 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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Ondansetron Tablets are and what they are used for
2. What you need to know before you take Ondansetron Tablets
3. How to take Ondansetron Tablets
4. Possible side effects
5. How to store Ondansetron Tablets
6. Contents of the pack and other information

1. What Ondansetron Tablets are and what they are used for

This medicine contains an active substance called Ondansetron hydrochloride dihydrate which belongs to a group of medicines called anti-emetics.

Ondansetron tablets are used for:

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

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

Ondansetron should start to work within one or two hours of taking a dose. You must talk to a doctor if you do not feel better or if you feel worse.

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

Do not take Ondansetron Tablets if you:

- are allergic (hypersensitive) to Ondansetron or to any of the other ingredients of this medicine (listed in Section 6)
- are taking apomorphine (used to treat Parkinson's disease)

If you are not sure, talk to your doctor, nurse or pharmacist before taking Ondansetron tablets.

Warnings and Precautions

Talk to your doctor, nurse or pharmacist before taking Ondansetron tablets if you:

- have a blockage in your gut or suffer from severe constipation
- have liver problems
- have ever had 'heart problems' (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- have an uneven heartbeat (arrhythmia)
- are allergic to medicines similar to Ondansetron such as granisetron or palonosetron
- have problems with the levels of salts in your blood such as potassium, sodium and magnesium

The use of buprenorphine together with ondansetron can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Ondansetron Tablets'). If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before taking Ondansetron tablets.

Other medicines and Ondansetron tablets

Tell your doctor, nurse or pharmacist if you are taking, 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, tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines used to treat epilepsy e.g. phenytoin, carbamazepine
- rifampicin used to treat infections such as tuberculosis (TB)
- pain killer e.g. tramadol
- anti-arrhythmic medicines used to treat an uneven heart beat
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines
- cancer medicines especially anthracyclines and trastuzumab
- antibiotics such as erythromycin or ketoconazole
- medicines that affect the heart (such as haloperidol or methadone)
- 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.
- buprenorphine/ naloxone (used to treat opioid overdose). These medicines may interact with ondansetron and 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 are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having Ondansetron tablets.

Tell your doctor or pharmacist immediately if you get any of these symptoms during and after the treatment with Ondansetron

- if you experience sudden chest pain or chest tightness (myocardial ischemia).

Pregnancy and breast feeding

Pregnancy:

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

Breast-feeding:

There is insufficient information on the excretion of ondansetron/metabolites in human milk or the effects of ondansetron on milk production. A risk to the newborns/infants cannot be excluded. Ondansetron should not be used during breast-feeding.

Driving and using machines

It is not expected that Ondansetron will affect your ability to drive; however, if any of the side effects (listed section 4) affect you (e.g. dizziness, blurred vision) caution is advisable. **Do not drive or operate machines if you are feeling unwell.**

Ondansetron tablets contain Lactose

- If you have been previously told by your doctor that you have intolerance to some sugars (such as lactose), contact your doctor before taking this medicinal product.

3. How to take Ondansetron Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. The dose you have been prescribed will depend on the treatment you are having.

The tablets should be swallowed whole with a little glass of water.

To prevent nausea and vomiting from chemotherapy or radiotherapy

Adults:

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.

If your chemotherapy or radiotherapy is likely to cause severe nausea and vomiting, you may be given more than the usual dose of Ondansetron. Your doctor will decide this.

FLAT DIMENSION = 140 x 480mm
 FOLDED DIMENSION = 140 x 30mm

Children and Adolescents (6 months to 17 years):**To prevent nausea and vomiting from chemotherapy only**

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:**Adults**

The usual adult dose is 16 mg given an hour before your operation.

Children aged over 1 month and adolescents

It is recommended that Ondansetron is given as an intravenous injection (medicines given into one of your veins).

Patients with moderate or severe liver disease

- Total daily dose should not be more than 8 mg. Ondansetron tablets should start within one or two hours of taking a dose. If you have blood tests to check how your liver is working, this medicine may affect the results.

If you are sick (vomit) within one hour of taking a dose

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

If you take more Ondansetron tablets than you should

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 tablets

If you miss a dose and feel sick or vomit:

- take Ondansetron tablets as soon as possible, then
- take your next tablet 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 as shown on the label
- do not take a double dose to make up for a forgotten dose.
- Important: A minimum time interval of 12 hours must be allowed between doses

If you have any further questions on the use of this medicine, ask your doctor, nurse 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 tell your doctor immediately if you suffer from any of the following:

- **Allergic reaction:** Symptoms of which may include sudden wheeziness and chest pain or chest tightness; swelling your eyelids, face, lips, mouth or tongue, skin rash-red spots or lumps under your skin (hives) anywhere on your body (also known as nettle rash or urticaria); or collapse.
- **Myocardial ischemia**
Signs include:
 - sudden chest pain or
 - chest tightness

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider:

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
- Slow or uneven heart beat
- Low blood pressure which can make you feel lightheaded or dizzy
- Chest pain
- Fits, unusual body movements or shaking

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

- Feeling dizzy or light headed during IV administration
- 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.
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis)

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 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 Tablets

- Keep this medicine out of the sight and reach of children
- Do not store above 25°C. Store in the original package.
- Do not use the tablets after the expiry date shown on the carton or label after (EXP). The expiry date refers to the last date of that month.
- Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Ondansetron tablets contain**

- The active substance in Ondansetron tablets is Ondansetron (as Ondansetron hydrochloride dihydrate).
- The other ingredients in Ondansetron tablets are – lactose, pregelatinised starch, microcrystalline cellulose, magnesium stearate, hypromellose, titanium dioxide (E171) and ferric oxide yellow (E172).

What Ondansetron tablets look like and contents of the pack.

- Ondansetron 4 mg tablets are yellow coloured, oval biconvex, film coated tablets debossed with 'BL' on one face and '4' on the other.
- Ondansetron 8 mg tablets are yellow coloured, oval biconvex, film coated tablets debossed with 'BL' on one face and '8' on the other.
- The tablets are supplied in packs containing 10, 30 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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