

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 about your illness or your medicine, 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

The active ingredient in your tablets, ondansetron, 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, nurse, or pharmacist if you would like any further explanation about these uses.

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

Do not take Ondansetron Tablets if:

- you are taking apomorphine (used to treat Parkinson's disease).
- you are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6).

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

Warnings and precautions

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

- you are allergic to medicines similar to ondansetron such as granisetron or palonosetron.
- you have a blockage in your gut.
- you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- you have an uneven heart beat (arrhythmias)
- you suffer from any liver problems.
- you have problems 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 Ondansetron Tablets.

Other medicines and Ondansetron Tablets

Tell your doctor 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

Ondansetron Tablets may have an effect on other drugs or other drugs may have an effect on Ondansetron Tablets.

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

- Anti-arrhythmic medicines such as amiodarone used to treat an uneven heartbeat.
- Phenytoin or carbamazepine, used to treat epilepsy.
- Rifampicin, an antibiotic used to treat infections such as tuberculosis (TB).
- Antibiotics such as erythromycin or ketoconazole.
- Tramadol, a pain relieving medicine.
- Beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines.
- Medicines that affect the heart (such as haloperidol or methadone).
- Cancer medicines (especially anthracyclines and trastuzumab).
- 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.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before having ondansetron tablets.

Pregnancy and breast-feeding

If you are already pregnant or breast-feeding, 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.

Pregnancy

Only use Ondansetron Tablets 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 Tablets 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).

Breast-feeding

Do not take Ondansetron Tablet if you are breast-feeding, because small amounts pass into the mother's milk.

Ondansetron Tablets contain lactose monohydrate

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

3. How to take Ondansetron Tablets

Always take Ondansetron Tablets 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.

To prevent nausea and vomiting from chemotherapy or radiotherapy

On the day of chemotherapy or radiotherapy

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

On the following days

- the recommended 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 recommended 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 ondansetron 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 Tablets than you should

If you or your child take more Ondansetron Tablets 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.

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

4. Possible side effects

Like all medicines, Ondansetron Tablets can cause side effects, although not everybody gets them.

Allergic reactions

If you have an allergic reaction, stop taking it and see a doctor straight away. The signs may include:

- 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
- slower heart rate

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 Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use Ondansetron Tablets after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.
- Store in the original package. Keep blister in the outer carton.
- If your doctor tells you to stop taking Ondansetron Tablets, it is important to return any which are left over to your pharmacist.
- 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 Tablets contain

- The active ingredient in Ondansetron Tablets is ondansetron hydrochloride dihydrate. Each Ondansetron film-coated tablet contains ondansetron 4 mg or 8 mg.
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, maize starch, magnesium stearate, hypromellose, titanium dioxide E171, macrogol.

What Ondansetron Tablets looks like and contents of the pack

- Ondansetron 4 mg Tablets are white, circular, biconvex, film coated tablet marked '4' on one side, plain on the other
- Ondansetron 8 mg Tablets are white, circular, biconvex, film coated tablet marked '8' on one side and with a deep breakline on the other.

Ondansetron Tablets come in:

- Blister strips comprising PVC/PVdC/Aluminium foil enclosed in an outer carton. Pack sizes of 10, 30, or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

Manufacturer:

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

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