



Ondansetron

4 mg and 8 mg Orodispersible Tablets

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

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

Ondansetron Orodispersible Tablets contain a medicine called ondansetron. This belongs to a group of medicines called anti-emetics. Ondansetron Orodispersible Tablets are a special type of tablets that dissolves very quickly when put on top of the tongue.

Ondansetron Orodispersible Tablets are 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 Orodispersible Tablets

Do not take Ondansetron Orodispersible 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).

Warnings and precautions

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

- 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 are allergic to medicines similar to ondansetron, such as granisetron or palonosetron,
- you have liver problems,
- you have a blockage in your gut,
- 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 applies to you, talk to your doctor, nurse or pharmacist before taking Ondansetron Orodispersible Tablets.

Other medicines and Ondansetron Orodispersible 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 Orodispersible Tablets can affect the way some medicines work. Also some other medicines can affect the way Ondansetron Orodispersible Tablets works.

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

- carbamazepine or phenytoin used to treat epilepsy,
- rifampicin used to treat infections such as tuberculosis (TB),

- antibiotics such as erythromycin or ketoconazole,
- anti-arrhythmic medicines used to treat an uneven heartbeat,
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines,
- tramadol, a pain killer,
- 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 or escitalopram,
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine or duloxetine

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having Ondansetron Orodispersible Tablets.

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

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

Pregnancy, breast-feeding and fertility

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 Orodispersible 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). 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 Orodispersible Tablets. If you are a woman of childbearing potential you may be advised to use effective contraception.

Do not breast-feed if you are taking Ondansetron Orodispersible Tablets. This is because small amounts pass into the mother's milk.

Driving and using machines

Ondansetron Orodispersible Tablets should not affect your ability to drive or operate machinery. However, if you feel dizzy or drowsy or unable to concentrate after taking Ondansetron Orodispersible Tablets, do not drive or operate machinery until these effects wear off.

Ondansetron Orodispersible Tablets contain aspartame

This medicine contains aspartame (which is a source of phenylalanine). If you have an inherited illness called phenylketonuria speak to your doctor before taking this medicine.

3. How to take Ondansetron Orodispersible Tablets

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 dose you have been prescribed will depend on the treatment you are having.

Place the orodispersible tablet on top of the tongue, where it will disperse quickly and then swallow.

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 or 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:

Tablets are not a suitable dosage form for this age group.

Ondansetron in injectable form is recommended for children aged over 1 month and adolescents.

Patients with moderate or severe liver problems

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

Ondansetron Orodispersible 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 Orodispersible Tablets than the label says.

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

If you take more Ondansetron Orodispersible Tablets than you should

If you or your child accidentally take more Ondansetron Orodispersible Tablets than you should, contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there are any Ondansetron Orodispersible Tablets left or not.

If you forget to take Ondansetron Orodispersible Tablets

If you miss a dose and feel sick or vomit:

- take a Ondansetron Orodispersible 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 stop taking Ondansetron Orodispersible Tablets

Do not stop taking Ondansetron Orodispersible Tablets unless your doctor tells you to.

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.

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:

- 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 Orodispersible 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 heartbeat,
- 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, nurse 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 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 Orodispersible Tablets

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

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.

This medicinal product does not require any special storage conditions.

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 Orodispersible Tablets contain

The active substance is ondansetron. Each orodispersible tablet contains 4mg or 8mg ondansetron.

The other ingredients are: mannitol, silica, colloidal anhydrous, basic butylated methacrylate copolymer, mannitol granular, crospovidone, aspartame (E951), flavour-strawberry and magnesium stearate.

What Ondansetron Orodispersible Tablets look like and contents of the pack

Ondansetron 4mg Orodispersible Tablets are round, white to off-white, flat, bevelled edged, tablets plain on both the surfaces, having strawberry odour.

Ondansetron 8mg Orodispersible Tablets are round, white to off-white, flat, bevelled edged, tablets plain on one surface and "8" engraved on opposite surface, having strawberry odour.

Ondansetron Orodispersible Tablets are available in blisters of 7, 10, 14, 15, 20, 28, 30, 56, 60, 84, 90, 100, 112 and 120.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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