

Package leaflet: Information for the user
Ondansetron 4mg and 8mg Film-coated Tablets
(Ondansetron)

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, please 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.

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
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6. Contents of the pack and other information

The name of your medicine is Ondansetron 4 mg Film-Coated Tablets and 8 mg Film-Coated Tablets (also referred to as Ondansetron Tablets throughout this leaflet).

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

Ondansetron tablets contain a medicine called ondansetron. This 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 (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).
- If you are allergic (hypersensitive) to ondansetron or any of the other ingredients in Ondansetron tablets (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, nurse or pharmacist before taking Ondansetron Tablets:

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

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken or might take 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, 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 heart beat
- 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, 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, nurse or pharmacist before having Ondansetron tablets.

Pregnancy and Breast-feeding

You should not use Ondansetron Tablets during the first trimester of pregnancy. 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). 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 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 tablets. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

Ondansetron Tablets contain lactose monohydrate

This medicinal product contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, check with your doctor before taking this medicinal product.

3. How to take Ondansetron Tablets

Always take Ondansetron Tablets exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure. The dose that 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 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 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 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.

4. Possible side effects

Like all medicines, Ondansetron 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.

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 national reporting systems listed below:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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 the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not take Ondansetron Tablets if you notice they are discoloured (they should be pale yellow).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ondansetron Tablets contain

- The active substance is Ondansetron (as Ondansetron hydrochloride dihydrate)
- Each tablet contains either 4mg or 8mg Ondansetron (as Ondansetron hydrochloride dihydrate)
- The other ingredients are lactose monohydrate, microcrystalline cellulose (E460(i)), pregelatinised starch, magnesium stearate, hypollose, propylene glycol (E1520), sorbitan oleate (E494), sorbic acid (E200), vanillin and quinolone yellow (E104).

What Ondansetron Tablets look like and contents of the pack

Ondansetron 4mg Film-Coated Tablets are pale yellow, round, biconvex, film-coated tablets with '41' embossed on one side. Ondansetron 8mg Film-Coated Tablets are pale yellow, round, biconvex, film-coated with '42' embossed on one side.

Ondansetron 4mg tablets are available in blister packs of 7, 14, 15, 28, 30 or 100 tablets. Ondansetron 8mg tablets are available in blister packs of 7, 10, 14, 28, 30 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder in the UK

Wockhardt UK Ltd, Ash Road North, Wrexham LL13 9UF, UK

Marketing Authorisation Holder in Malta

Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary, Ireland

Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham LL13 9UF, UK

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:

Product Name	Reference Number
Ondansetron 4mg Film-coated Tablets	PL 29831/0155
Ondansetron 8mg Film-coated Tablets	PL 29831/0156

This is a service provided by the Royal National Institute of Blind People.

For patients in Malta please call UK +44 1978 661261.

This medicinal product is authorised in the Member States of the EEA under the following names:

UK and Malta: Ondansetron 4mg and 8mg Film-coated Tablets

This leaflet was last revised in 09/2019.