

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

Package leaflet: Information for the user

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 of the 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 Tablet is and what it is 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 Tablet is and what it is used for

Ondansetron belongs to a group of medicines known as 'antiemetics and antinauseants'. These prevent feelings of sickness (nausea) or being sick (vomiting) that may occur after certain medical or surgical treatments.

Your doctor or nurse may give you Ondansetron Tablets to prevent you from or to treat you for feeling or being sick when you:

- are on chemotherapy (adults and children) and radiotherapy (adults only) that can cause nausea and vomiting.
- undergo surgical treatment (adults only).

2 What you need to know before you take Ondansetron Tablets

Do not take Ondansetron Tablets:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Ondansetron Tablets:

- if you are allergic to similar medicines known as 5HT₃ receptor antagonists e.g. granisetron or palonosetron
- if you have liver disease
- if you have a blockage in your gut
- if you have had surgery on your adenoids or tonsils
- 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 have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

If any of the above apply to you, talk to your doctor who will decide what to do.

Other medicines and Ondansetron Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines may interact with Ondansetron Tablets:

- Tramadol. The effect of pain relief from Tramadol may be reduced whilst you are taking Ondansetron Tablets.

- Phenytoin and carbamazepine (usually used to treat epilepsy)
- Rifampicin (a type of antibiotic, often used for the treatment of tuberculosis)
- Medicines that affect the heart (such as haloperidol or methadone)
- Medicines used to treat an uneven heart beat (anti-arrhythmics)
- Beta-blocking medicines (used to treat heart problems, eye problems, anxiety or for prevention of migranes)
- Cancer medicines (especially anthracyclines and trastuzumab)
- Medicines used to treat infections (erythromycin, ketoconazole)
- Medicines used to treat depression and/or anxiety (SSRIs and SNRIs) e.g. fluoxetine, paroxetine, citalopram, venlafaxine.

Pregnancy and breast-feeding

- 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). 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.
- Ondansetron may pass into breast milk, therefore breast-feeding is not recommended in mothers taking Ondansetron Tablets.

Driving and using machines

Ondansetron Tablets should not affect your ability to drive or use machinery.

Important information about some of the ingredients of Ondansetron Tablets

Ondansetron Tablets contain **lactose** monohydrate, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Ondansetron 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. Ondansetron Tablets should be swallowed whole with a little water.

Ondansetron Tablets should start to work within 1 to 2 hours of taking a dose. If you are sick within 1 hour of taking Ondansetron Tablets you should talk to your doctor who will tell you what you should do. If you continue to feel or be sick whilst taking the tablets, tell your doctor.

For patients receiving chemotherapy and/or radiotherapy that causes nausea or vomiting

Adults (including the elderly)

The usual dose is 8 mg 1-2 hours before you are treated with chemotherapy or radiotherapy, followed by 8 mg 12 hours later.

After the first 24 hours following chemotherapy, Ondansetron Tablets can be given to prevent further nausea or vomiting. The usual dose for oral administration is 8 mg twice daily, which can be given for up to 5 days.

Children aged over 6 months and adolescents

The doctor will decide the dose.

- the usual dose for a child is 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 dose is 16 mg taken one hour before the operation or 8 mg taken one hour before the operation followed by two further doses of 8 mg at eight hourly intervals.

Children aged over 1 month and adolescents

It is recommended that an injection is given.

Patients with liver disease

In patients with moderate or severe liver problems a total daily dose of 8 mg should not be exceeded.

If you take more Ondansetron Tablets than you should

It is important to stick to the dose on the label of your medicine. Taking more than this could make you ill.

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 forget to take a dose and do not feel sick take the next day's tablet at the usual time. If you forget to take a dose, and feel sick or are sick, take a tablet as soon as possible. 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, this medicine can cause side effects, although not everybody gets them.

If the following happens to you or your child, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- An allergic reaction causing swelling of the face, lips, tongue or throat, difficulting in breathing or swallowing, skin rash
- 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 or chest pain
- Fits
- Unusual body movement or shaking

Rare (may affect up to 1 in 1000 people)

- Feeling dizzy or lightheaded
- Blurred vision
- Disturbances in heart rhythm (sometimes causing a sudden loss of consciousness)

Very rare (may affect up to 1 in 10000 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 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 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 carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store your tablets in the original package in order to protect from light.

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 contains

- The active substance is ondansetron (as hydrochloride dihydrate). Each tablet contains 4 mg or 8 mg of ondansetron.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, maize starch, magnesium stearate. The ingredients of the film-coating on the tablets are lactose monohydrate, hypromellose, titanium dioxide E171, macrogol and sodium citrate dihydrate E331.

What Ondansetron Tablets look like and contents of the pack

Ondansetron Tablets are white to off-white, round biconvex film-coated tablets with PA engraved on one side and 933 (4 mg tablets) or 934 (8 mg tablets) on the other side.

Ondansetron Tablets are available in blister packs containing 6, 10, 15 or 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

PLIVA Pharma Ltd., Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX, United Kingdom.

Manufacturer

Teva Operations Poland Sp. z.o.o., Ul. Mogilska 80, 31-456 Krakow, Poland.

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