Package leaflet: Information for the patient

Ondansetron 4 mg film-coated tablets
Ondansetron 8 mg 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, 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.

What is in this leaflet

1. What Ondansetron is and what it is used for

Ondansetron belongs to a group of drugs called anti-emetics, which prevent nausea and vomiting (feeling sick or being sick)
Ondansetron is used:
- to treat nausea (feeling sick) and vomiting (being sick) caused by receiving chemotherapy or radiotherapy in adults, children and adolescents aged 6 month to 17 years.
- to prevent nausea and vomiting following surgical operations in adults.

2. What you need to know before you take Ondansetron

Do not take Ondansetron
- if you are allergic to ondansetron or any of the other ingredients of this medicine (listed in section 6).
- if you are being given apomorphine (a medicine to treat Parkinson's disease).

Must not be used in children with a body surface area of less than 0.6 m^2 or with a body weight up to 10 kg. More suitable dosage forms with a lower active ingredient content are available for this patient group.

Warnings and precautions
Talk to your doctor or pharmacist before taking Ondansetron if you
- are allergic to medicines similar to ondansetron (5-HT_3-antagonists)
- have had heart problems, including an uneven heart beat (arrhythmias)
- have liver problems.
- have a blockage in your gut or if you suffer from severe constipation.
- have had surgery on your gut
- have had surgery on your adenoids or tonsils
- have problems with the levels of salts in your blood, such as potassium, sodium and magnesium

Other medicines and Ondansetron
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Ondansetron changes the effects and/or side effects of some medicines, including:
- Apomorphine (a medicine used to treat Parkinson's disease). There have been reports of a severe decrease in blood pressure and loss of consciousness when ondansetron was taken at the same time as apomorphine.
- Carbamazepine, Phenytoin (used in the treatment of epilepsy).
- Rifampicin (used in the treatment of tuberculosis).
- Tramadol (used to relieve moderate to moderately severe pain).
- Medicines that affect the heart such as certain cancer medicines (anthracyclines or trastuzumab) or QT interval prolonging medicines (that can cause a change in a ECG with the risk of life-threatening abnormal or irregular heartbeat).
- Selective serotonin reuptake inhibitors (SSRIs) for the treatment of depression and/or anxiety such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram.
- Selective norepinephrine reuptake inhibitors (SNRIs) for the treatment of depression and/or anxiety such as venlafaxine or duloxetine.

Pregnancy and breast-feeding
You should not use Ondansetron during the first trimester of pregnancy. 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 Ondansetron. 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.
This is because small amounts pass into mother's milk. Ask your doctor for advice.

Driving and using machines
Ondansetron has no or negligible influence on your ability to drive or operate machinery.

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

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

3. How to take Ondansetron

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 recommended dose is:

To treat nausea and vomiting caused by receiving chemotherapy or radiotherapy:
- **Adults (including the elderly):**

8 mg taken 1 to 2 hours before chemotherapy or radiotherapy, followed by 8 mg 12 hours later.
24 hours after chemotherapy or radiotherapy, 8 mg twice a day may be taken for up to 5 days.

- **Use in children (aged over 6 months) and adolescents**

Ondansetron may be given initially by a single injection into the vein over 15 minutes before chemotherapy, followed by tablets which may be given two to three times a day for up to 5 days

following chemotherapy. The dose of tablets will depend on the body size of your child and will be calculated by your doctor.

To prevent nausea and vomiting after an operation:

- **Adults (including the elderly):**

A dose of 16 mg can be taken one hour before the anaesthesia.
Alternatively, a dose of 8 mg can be taken one hour before the anaesthesia, followed by two further 8 mg doses at eight hourly intervals.

- **Use in children (aged over 1 month) and adolescents**

It is recommended that an intravenous injection containing Ondansetron should be given.

Patients with liver problems
The total daily dose should not exceed 8 mg.

Ondansetron should start to work within one to two hours of taking the dose. If you vomit the dose back within one hour, take another dose. Otherwise, continue to take your tablets as on the label, but do not take more than your doctor has recommended. If you continue to feel sick then you should tell the doctor.

Method of administration
The tablets should be swallowed whole preferably with a drink of water.
Ondansetron 8 mg film-coated tablets: The score line is only to help you break the tablet, if you have difficulty swallowing it whole.

If you take more Ondansetron 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.

An overdose can cause temporary problem with your sight, severe constipation, feeling dizzy or faint.

If you forget to take Ondansetron
Do not take a double dose to make up for a forgotten dose.
If you forget to take a tablet and feel sick or vomit, take one as soon as you remember and then carry on as before. If you forget to take a tablet and do not feel sick, then wait until the next dose as on the label. Take the remaining doses at the correct time.

If you stop taking Ondansetron
Do not stop taking you medicine without talking to your doctor first even if you feel better.

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, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

Uncommon: may affect up to 1 in 100 people

- fits

Rare: may affect up to 1 in 1,000 people

- an allergic reaction causing (swelling of the face, lips, tongue or throat, difficulty in breathing or swallowing, skin rash)
- collapse

- disturbances in heart rhythm (sometimes causing a sudden loss of consciousness).

Very rare: may affect up to 1 in 10,000 people
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis)

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 with a medicine called cisplatin, otherwise this side effect is uncommon)

Uncommon: may affect up to 1 in 100 people
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes
- unusual body movements or shaking.
- hiccups
- low blood pressure, which can make you feel faint or dizzy
- uneven heart beat or chest pain
- slow heart rate

Rare: may affect up to 1 in 1,000 people
- feeling dizzy or light headed
- blurred vision

Very rare: may affect up to 1 in 10,000 people
- poor vision or temporary loss of eyesight predominantly after intravenous administration

Children and adolescents
The adverse event profiles in children and adolescents were comparable to that seen in adults.

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 HPRA Pharmacovigilance Website: www.hpra.ie.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ondansetron

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. 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 contains

- The active substance is ondansetron.
  Each film-coated tablet contains 4 mg ondansetron (as ondansetron hydrochloride dihydrate).
  The active substance is ondansetron.
  Each film-coated tablet contains 8 mg ondansetron (as ondansetron hydrochloride dihydrate).

- The other ingredients are:
  - tablet core: lactose monohydrate, sodium starch glycolate, microcrystalline cellulose, pregelatinised starch, magnesium stearate,
  - coating: hypromellose, titanium dioxide (E171), macrogol (400 & 6000) and yellow iron oxide (E172).

What Ondansetron looks like and contents of the pack

- Ondansetron 4 mg film-coated tablets are yellow, oblong film-coated tablets engraved "4" on one side and plain on the other.
- Ondansetron 8 mg film-coated tables are yellow, oblong film-coated tablets engraved "8" on one side and scoreline on the other.
- Ondansetron 4 mg film-coated tablets are available in pack sizes of 2, 4, 5, 6, 10, 15, 30, 50, 100 & 500 film-coated tablets.
- Ondansetron 8 mg film-coated tablets are available in pack sizes of 2, 4, 5, 6, 9, 10, 15, 18, 30, 50, 100 & 500 film-coated tablets.
  Not all pack sizes may be marketed.

Marketing Authorisation Holder
Teva Pharma B.V., Swensweg 5, 2031GA Haarlem, The Netherlands

Manufacturer
Pharmachemie BV, Swensweg 5, Postbus 522, 2003 RN Haarlem, The Netherlands
TEVA Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hungary
Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143 Blaubeuren, Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Czech Republic: Ondansetron-Teva 8mg
Denmark: Ondansetron Teva 4mg & 8mg Filmovertrukne tabletter
Germany: Ondansetron-GRY® 4 mg & 8 mg Filmtabletten
Ireland: Ondansetron 4 mg and 8 mg Film-coated Tablets
Italy: Ondansetron Teva 4mg & 8mg Compessa rivestita con film
Latvia: Ondansetron-Teva 8mg Tabletes
Portugal: Ondansetron 4mg & 8mg Compimido revestido
Slovakia: Ondansetron-Teva 4mg & 8mg
Spain: Ondansetron TEVA 4mg & 8mg comprimidos recurbiertos con pelicula EFG
Sweden: Ondansetron Teva 4mg & 8mg Filmdragerad tablet
The Netherlands: Ondansetron 4 & 8 PCH, filmomhulde tabletten 4mg & 8mg
UK (NI): Teva Ondansetron 4mg & 8mg Film-Coated Tablets

This leaflet was last revised in July 2022.