

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
2. What you need to know before you take Ondansetron
3. How to take Ondansetron
4. Possible side effects
5. How to store Ondansetron
6. Contents of the pack and other information

1. What Ondansetron is and what it is used for

Ondansetron belongs to a group of medicines called anti-emetics, drugs against feeling sick (nausea) or being sick (vomiting).

This medicine is used for:

- preventing nausea (feeling sick) and vomiting (being sick) caused by chemotherapy (in adults and children) or radiotherapy for cancer (adults only)
- preventing nausea and vomiting after surgery (adults only).

2. What you need to know before you take Ondansetron

Do not take Ondansetron:

- if you are taking apomorphine, a medicine used to treat Parkinson's disease
- if 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 or pharmacist before taking Ondansetron:

- 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 heartbeat (arrhythmias)
- if you are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- if you have liver problems
- if you suffer from any blockage in your gut or if you have severe constipation
- if your blood levels of potassium or magnesium are reduced
- if you are having your tonsils out.

Other medicines and Ondansetron

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.

In particular, tell your doctor or pharmacist:

- if you are taking phenytoin, carbamazepin (used to treat epilepsy or other illnesses), or rifampicin (used to treat certain infections): the ondansetron blood concentrations are decreased
- if you are taking tramadol (used to treat pain): the effect of tramadol may be reduced
- if you are taking medicines used to treat heart problems such as anti-arrhythmic medicines (e.g. amiodarone) and beta-blockers (e.g. timolol or atenolol)
- if you are taking any cancer medicines which are known to have toxic effects on the heart (especially anthracyclines e.g. daunorubicin, doxorubicin or trastuzumab). These medicines may not be used together with ondansetron as they may increase the risk of irregular heartbeat
- if you are taking serotonergic drugs (including SSRIs and SNRIs), used to treat major depression and other mental disorders
- if you are taking apomorphine (a medicine used to treat Parkinson's disease), because severe drop in blood pressure and loss of consciousness were reported when Ondansetron was used with apomorphine.

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 Ondansetron.

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 a woman of childbearing potential you may be advised to use effective contraception.

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

Driving and using machines

Ondansetron has no or negligible effect on the ability to drive or use machines.

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 medicine.

3. How to take Ondansetron

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Swallow each tablet whole with a little water.

Your doctor will decide on the correct dose of ondansetron therapy for you. The dose varies depending on why you are being given ondansetron and on your liver function.

Patients receiving chemotherapy and/or radiotherapy that causes nausea and vomiting

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

The recommended dose is 8 mg 1 to 2 hours before chemotherapy, followed by 8 mg 12 hours later. After the first 24 hours following chemotherapy, ondansetron tablets can be given to prevent nausea and vomiting. The usual dose is 8 mg twice a day, which can be taken up to 5 days.

- **Children aged over 6 months and adolescents (less than 18 years of age):**

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

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

The usual adult dose is 16 mg before the operation.

- **Children aged over 1 month and adolescents (less than 18 years of age):**

It is recommended that ondansetron is given as an intravenous injection.

Patients with moderate or severe liver problems

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

If you notice that the effect of ondansetron is too strong or too weak, talk to your doctor or pharmacist.

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.

If you forget to take Ondansetron

If you forget a dose and feel sick or vomit, take a tablet as soon as possible and then carry on as before. Do not take a double dose to make up for a forgotten dose. If you miss a dose but not feel sick take the next dose as on the label.

If you stop taking Ondansetron

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.

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.

Some side effects could be serious

Stop taking this medicine and seek medical help immediately if you or your child experience any of the following:

Allergic reactions

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 heartbeat

- chest pain
- fits
- unusual body movements or shaking.

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

- dizziness or light-headedness
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: 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 medicine 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. Content of the pack and other information

What Ondansetron contains

- The active substance is ondansetron.
Each film-coated tablet contains 4 mg of ondansetron (as hydrochloride dihydrate).
Each film-coated tablet contains 8 mg of ondansetron (as hydrochloride dihydrate).
- The other ingredients are anhydrous lactose, microcrystalline cellulose, pregelatinised (maize) starch, magnesium stearate, hypromellose, lactose monohydrate, titanium dioxide (E171), triacetin, iron oxide yellow (E172).

What Ondansetron looks like and contents of the pack

Yellow, oval shaped, film-coated tablets, plain on both sides.

The film-coated tablets are packed in PVC/PVDC/aluminium blisters and inserted in a carton.

Pack sizes:

6, 10, 15, 20, 30, 50, 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
LEK S.A., ul. Domaniewska 50C, 02-672 Warsaw, Poland.
S.C. Sandoz S.R.L., Str. Livezeni nr. 7A, RO-540472 Targu-Mures, Romania.

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

Ireland	Ondansetron 4 mg film-coated tablets
	Ondansetron 8 mg film-coated tablets
United Kingdom	Ondansetron 4 mg Film-coated Tablets
	Ondansetron 8 mg Film-coated Tablets

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