

Package leaflet: Information for the user
Ondansetron 4mg/5ml Syrup
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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (See section 4).

What is in this leaflet

1. What Ondansetron Syrup is and what it is used for
2. What you need to know before you take Ondansetron Syrup
3. How to take Ondansetron Syrup
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1. What Ondansetron Syrup is and what it is used for

Ondansetron 4mg/5ml Syrup belongs to a group of medicines called anti-emetics, also known as serotonin 5HT₃ antagonists (called Ondansetron Syrup throughout the rest of this leaflet).

Ondansetron Syrup is taken if you are feeling sick (nausea) or being sick (vomiting) after you have had chemotherapy, radiotherapy, or an operation.

2. What you need to know before you take Ondansetron Syrup

Do not take Ondansetron Syrup

- 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 precaution

Talk to your doctor, pharmacist or nurse before taking Ondansetron Syrup

- if you are allergic (hypersensitivity) to medicines similar to ondansetron such as dolasetron, granisetron and palonosetron;
- if you have a blockage in your gut or bowel or if you have constipation;
- 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 your liver;
- if you know that the levels of sodium, potassium, magnesium or chloride in your body are very low or very high.

Other medicines and Ondansetron Syrup

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

Make sure your doctor knows if you are taking a medicine listed here:

- **Beta blockers** (used to treat certain heart or eye problems, anxiety or prevent migraines);
- **Atenolol** to treat high blood pressure or angina (pains in your chest): use with ondansetron may cause a change to your heart rate;
- **Anti-arrhythmics** such as **amiodarone** to control your heart rate: use with ondansetron may cause a change to your heart rate;
- **Phenytoin** and **carbamazepine** to treat epilepsy, or **rifampicin** to treat tuberculosis: ondansetron may not work as well;
- **Tramadol** a strong painkiller: ondansetron may stop the tramadol working properly;
- **Haloperidol** or **Methadone** medicines that affect the heart;
- **Antibiotics** such as **erythromycin** to treat bacterial infections and **Antifungals** such as **ketoconazole** to treat fungal infections: use with ondansetron may increase the risk of irregular heartbeats or changes to your heart rate;
- **Cardiotoxic drugs** such as some cancer medicines including anthracyclines (e.g. doxorubicin and daunorubicin) and trastuzumab: use with ondansetron may increase the risk of irregular heartbeats or changes to your heart rate;
- **SSRIs** (selective serotonin re-uptake inhibitors) used to treat depression and/or anxiety including **fluoxetine**, **paroxetine**, **sertraline**, **fluvoxamine**, **citalopram**, **escitalopram**;
- **SNRIs** (serotonin noradrenaline re-uptake inhibitors) used to treat depression and/or anxiety including **venlafaxine**, **duloxetine**: use with ondansetron may cause side effects to get worse.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Only use Ondansetron Syrup 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 Syrup 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 Syrup. If you are a woman of childbearing potential you may be advised to use effective contraception.

Breast-feeding

Do not breast-feed if you are taking Ondansetron. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

Driving and using machines

Ondansetron Syrup does not affect your ability to drive or use machines.

Ondansetron Syrup contains

This medicine contains 2 mg sodium benzoate in 1 ml, which is equivalent to 2 mg/ml. Benzoic salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine contains Xylitol (E 967) which may have a laxative effect and has a calorific value of 2.4 kcal/g xylitol.

This medicine contains 13.5 mg propylene glycol in each 5ml which is equivalent to 2.7 mg/ml.

3. How to take Ondansetron Syrup

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

Do not mix Ondansetron syrup with anything (not even water) before swallowing it.

The recommended dose is- Adults and the elderly

During chemotherapy or radiotherapy

- the usual dose is two 5ml spoonfuls (8mg ondansetron);
- this is taken 1 to 2 hours before your therapy starts;
- take two 5ml spoonfuls (8mg ondansetron) 12 hours later;
- take two 5ml spoonfuls (8mg ondansetron) twice a day for up to five days after the day of your chemo- or radiotherapy;
- if your chemotherapy is expected to make you feel, or be, very sick take 6 spoonfuls (24mg ondansetron) before therapy. Your doctor may recommend taking 12mg of dexamethasone at the same time;
- you should not take more than 32mg over a 24 hour period.

If you are having an operation

- **either** take four 5ml spoonfuls (16mg ondansetron) one hour before your anaesthetic, **or** two 5ml spoonfuls (8mg ondansetron) one hour before your anaesthetic followed by two 5ml spoonfuls at 8 hours and 16 hours after your first dose.

Use in children and adolescents (aged 6 months and above)

During chemotherapy or radiotherapy

- The dose depends on the weight or body surface area of the child;
- Your doctor will tell you the actual dose for your child;
- Make sure the child takes the medicine as the doctor says;
- A dose range of half a 5ml spoonful (2mg ondansetron) to two 5 ml spoonfuls (8mg ondansetron) every 12 hours for up to five days is permitted.

If your child is having an operation

- Ondansetron Syrup is not normally given to children before an operation.

Patients with liver disease

- The maximum dose is two 5ml spoonfuls (8mg ondansetron) each day.

If you take more Ondansetron Syrup than you should

If you or your child take more Ondansetron Syrup than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. In an event of overdose you may experience constipation, difficulty in seeing, low blood pressure, feeling dizzy, feeling sick, loss of consciousness, abnormal changes to ECG.

If you forget to take Ondansetron Syrup

If you forget to take a dose, take another as soon as you remember. Then take your next dose at the normal time.

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, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you have any of the following rare side effects while taking your medicine tell your doctor immediately or go to hospital straight away:

- severe allergic reaction which may include a red and lumpy skin rash (hives), difficulty with breathing, sudden wheezing, swelling of your face, mouth, lips or eyelids, a high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away;**
- uneven, fast or slow heartbeat (palpitations);
- chest pain;
- irregular heartbeat;
- myocardial ischemia
signs include:
 - sudden chest pain or
 - chest tightness.

Other side effects which may occur

Very common (may affect more than 1 in 10 people)

- headache.

Common (may affect up to 1 in 10 people)

- constipation;
- flushing or feeling warm.

Uncommon (may affect up to 1 in 100 people)

- fits (seizures);
- muscle weakness;
- problems controlling movement or problems with the movement of your eyes;
- hiccups;

- low blood pressure, which can make you feel faint or dizzy;
- uneven heart beat;
- chest pain;
- changes to liver function test results (if you take Ondansetron syrup with a medicine called cisplatin).

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

- feeling dizzy or light headed (usually when given by injection);
- changes to your vision such as blurred vision (usually when given by injection);
- 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, especially if you are also having chemotherapy (usually when given by injection).

If you need a **blood test** tell your doctor you are taking this medicine as it may affect the results.

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 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 Syrup

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

Do not use this medicine after the expiry date stated on the carton and bottle after “Exp”.

The expiry date refers to the last day of that month.

Once opened, use within 28 days.

There are no special storage conditions for your medicine.

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 Syrup contains

- The active substance is ondansetron (as the hydrochloride dihydrate). Each 5ml spoonful contains 4mg of ondansetron.
- The other ingredients are citric acid anhydrous, sodium citrate dihydrate, sodium benzoate (E211), xylitol (E967), strawberry flavour (containing propylene glycol (E1520)) and purified water.

What Ondansetron Syrup looks like and contents of the pack

Ondansetron Syrup is a clear solution in a brown glass bottle containing 50ml of the solution.

Marketing Authorisation Holder

Focus Pharmaceuticals Limited, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom.

Manufacturer

Penn Pharmaceutical Services Ltd, Tredegar, Gwent, NP22 3AA.

This leaflet was last revised in August 2023.