



Package Leaflet: Information for the user

Ondansetron 8mg/5ml Oral Solution

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 about your illness or your medicine, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you, or your child, only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Ondansetron oral solution is and what it is used for
- What you need to know before you take Ondansetron oral solution
- How to take Ondansetron oral solution
- Possible side effects
- How to store Ondansetron oral solution
- Contents of the pack and other information

1. WHAT ONDANSETRON ORAL SOLUTION IS AND WHAT IT IS USED FOR

Ondansetron 8mg/5ml oral solution (called Ondansetron oral solution in this leaflet) contains the active substance ondansetron hydrochloride. This belongs to a group of medicines called anti-emetics.

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

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 ORAL SOLUTION

Do not take Ondansetron oral solution if you or your child:

- are taking apomorphine (used to treat Parkinson's disease)
- are allergic (hypersensitive) to ondansetron or any of the other ingredients in this medicine (listed in Section 6)
- are in the first three months of your pregnancy.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Ondansetron oral solution if you or your child:

- have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- have an uneven heartbeat (arrhythmias)
- are allergic to medicines similar to ondansetron, such as granisetron or palonosetron
- have liver problems
- have a blockage in your gut
- have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.
- have depression or other conditions that are treated with antidepressants, or if you are taking painkillers such as opioids. The use of these medicines together with Ondansetron oral solution can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Ondansetron oral solution').

If you are not sure if any of the above apply, talk to your doctor, nurse or pharmacist before taking Ondansetron oral solution.

Other medicines and Ondansetron oral solution

Please tell your doctor, nurse or pharmacist if you, or your child, 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.

In particular, tell your doctor, nurse or pharmacist if you, or your child, 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 antifungals such as ketoconazole.
- Anti-arrhythmic medicines used to treat an uneven heartbeat.
- 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.
- Opioid/opiate medicines used to treat acute or chronic pain (e.g. buprenorphine).

Use of ondansetron with SSRIs, SNRIs and opioid/opiate medicines may cause serotonin syndrome, a potentially life-threatening reaction. The symptoms of serotonin syndrome may include a combination of the following: nausea (feeling sick), vomiting, agitation, confusion, diarrhoea, high temperature, increased blood pressure, excessive sweating, rapid heartbeat, hallucinations, loss of coordination, overactive reflexes and coma.

If you are not sure if any of the above apply to you or your child, talk to your doctor, nurse or pharmacist before taking Ondansetron oral solution.

Pregnancy and breast-feeding

You should **not** use Ondansetron oral solution during the first trimester of pregnancy. This is because it 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 oral solution. 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 the mother's milk.

Important information about some of the ingredients of Ondansetron oral solution

This medicine contains:

Sodium benzoate (E211): This medicine contains 10mg in each 5ml.

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Sorbitol (E420): This medicine contains 2.1g sorbitol in each 5ml.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Sodium: This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium-free'.

Ethanol: This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per 5ml.

3. HOW TO TAKE ONDANSETRON ORAL SOLUTION

Always take your medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The dose you or your child have been prescribed will depend on the treatment you are having.

- For oral use only. Take this medicine by mouth.
- To give the correct dose, use the syringe provided.
- Ondansetron oral solution should start to work within one or two hours of taking a dose.

To prevent nausea and vomiting from chemotherapy or radiotherapy

On the day of chemotherapy or radiotherapy

- The usual adult dose is 5ml (8mg) taken one to two hours before treatment and another 5ml (8mg) twelve hours afterwards.

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On the following days

- The usual adult dose is 5ml (8mg) taken 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.

- The usual dose for a child is up to 2.5ml (4mg) taken 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 10ml (16mg) before your operation.

Children aged 1 month and over and adolescents:

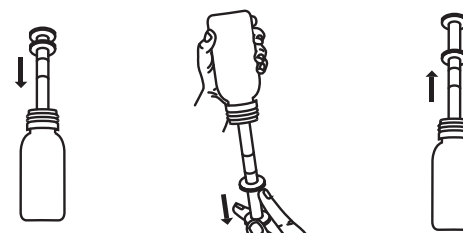
It is recommended that ondansetron is given as an injection.

Patients with moderate or severe liver problems

The total daily dose should not be more than 5ml (8mg).

Using the dosing syringe

- When you use the medicine for the first time, place the adaptor in the neck of the bottle.
- Push the syringe firmly into the adaptor in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. While holding the syringe in place, the plunger should be pulled down gently and the medicine drawn to the correct mark on the syringe. Your doctor will tell you the right dose for you or your child.
- Turn the bottle the right way up, remove the syringe from the adaptor by gently twisting the syringe.



- Place the end of the syringe into your mouth or the child's mouth and gently press the plunger down to slowly release the medicine.
- Repeat steps 2-5, as necessary, to give the full dose.
- After use replace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of reach of children.

If you are sick (vomit) within one hour of taking a dose

- Take the same dose again
- Otherwise, do not take more Ondansetron oral solution.

If you continue to feel sick, tell your doctor or nurse.

If you take more Ondansetron oral solution 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 oral solution

If you miss a dose and feel sick or vomit:

- Take Ondansetron oral solution as soon as possible, then take your next dose at the usual time.
- 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 soon as you remember. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

Stop taking Ondansetron oral solution immediately and see a doctor or go to hospital straightaway if:

- you or your child have an allergic reaction. Signs of an allergic reaction include: a rash, itching, problems swallowing or breathing, swelling of the lips, face, throat or tongue.

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 oral solution 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)

- 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.

Not known (frequency cannot be estimated from the available data)

- Myocardial ischemia (signs include sudden chest pain or chest tightness).

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 ORAL SOLUTION

- Store in the original package to protect from light. This medicinal product does not require any special temperature storage conditions.
- A slight yellowing of the solution upon storage is characteristic of this product.
- Once opened use within one month.
- 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 bottle and carton after 'Exp'. The expiry date refers to the last day of that month.
- 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 oral solution contains

- Each 5 ml of Ondansetron oral solution contains 8 mg of the active ingredient ondansetron (as hydrochloride dihydrate).
- The other ingredients are citric acid anhydrous (E330), sodium citrate dihydrate (E331), sodium benzoate (E211), sorbitol (E420), strawberry flavour (contains propylene glycol (E1520), lactic acid natural (E270), triacetin (E1518), ethanol) and purified water.

What Ondansetron oral solution looks like and contents of the pack

Ondansetron oral solution is a clear, colourless to light yellow solution with a strawberry odour supplied in an amber glass bottle containing 100ml and sealed with a plastic child-resistant and tamper evident cap. It comes with a dosing syringe marked per 0.25ml and a syringe adaptor.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.


Formats suitable for the blind and partially-sighted are available on request from the Marketing Authorisation Holder

Manufacturer

LABOMED PHARMACEUTICAL COMPANY S.A.
84 Ioannou Metaxa str.
19441, Koropi, Attica, Greece

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JOB INFORMATION		JOB SPECIFICATION		APPROVALS		
		Product Name: Ondansetron 8mg/5ml Oral Solution	Keyline Ref: UKL510 Dimensions: 190 x 360mm Folded Size: N/A Tabbed: N/A	Pharmacode: 159 EAN Code: N/A No. of Colours: 1 Page Number: 1 of 1	Third Party Approval Name: _____ Sign: _____ Date: _____	
Strength: 8mg/5ml	New Item Code: F5V98RBJ1	MAIN BODY TEXT Font Type: Univers Bold Font Size: 9pt		Regulatory Approval Name: _____ Sign: _____ Date: _____		
Pack Size: 100 ml	Previous Item Code: N/A	COLOURS Print Colours: BLACK Non-print Colours: KEYLINE				
Bottle Size: 100 ml	Supplier Code: CLS-26-00128					
Design Icon: N/A	Change Control No.: CR-00376					
ARTWORK VERSION: 9	PRINT VERSION: -					
Date: 26/09/22	Date: -					
Operator: Steve	Operator: -					