

Ondansetron 4mg/5ml oral solution

(Ondansetron hydrochloride dihydrate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

The name of your medicine is ondansetron 4mg/5ml oral solution. It will be referred to as ondansetron oral solution in this leaflet.

What is in this leaflet:

1. What ondansetron oral solution is and what it is used for
2. What you need to know before you take ondansetron oral solution
3. How to take ondansetron oral solution
4. Possible side effects
5. How to store ondansetron oral solution
6. Contents of the pack and other information

1. What ondansetron oral solution is and what it is used for

Ondansetron oral solution contains a medicine called ondansetron. This belongs to a group of medicines called anti-emetics.

Ondansetron oral solution is used for:

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

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 are taking apomorphine (used to treat Parkinson's disease)
 - you are allergic (hypersensitive) to ondansetron or any of the other ingredients in ondansetron oral solution (listed in Section 6).
- If you are not sure, talk to your doctor, nurse or pharmacist before taking ondansetron oral solution.

Warnings and precautions

Check with your doctor, nurse or pharmacist before taking ondansetron oral solution if:

- you have ever had heart problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles)
- you have an uneven heart beat (arrhythmias)
- you are allergic to medicines similar to ondansetron oral solution, such as granisetron or palonosetron
- you have liver problems
- you have a blockage in your gut
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.

If you are not sure if any of the above apply to you, 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 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 oral solution can affect the way some medicines work. Also some other medicines can affect the way ondansetron oral solution works.

In particular, tell your doctor, nurse or pharmacist if you 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 ketoconazole
- anti-arrhythmic medicines used to treat an uneven heart beat
- 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.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having ondansetron oral solution.

Pregnancy and breast-feeding

Only use 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 oral solution 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 oral solution. This is because small amounts pass into the mother's milk. Ask your doctor or midwife for advice.

Important information about some of the ingredients of ondansetron oral solution

Ondansetron oral solution contains 2.1g of sorbitol per 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.

Ondansetron oral solution contains 10mg of sodium benzote per 5ml which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

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

This medicine contains small amounts of ethanol (alcohol), less than 100 mg per 5 ml.

This medicine contains 0.0003mg of benzyl alcohol per 5ml. Benzyl alcohol may cause allergic reactions. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. There is an increased risk due to accumulation in young children.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings syndrome") in young children.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Ondansetron oral solution also contains 0.1023mg of propylene glycol.

3. How to take ondansetron oral solution

Always take ondansetron oral solution exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure. The dose you have been prescribed will depend on the treatment you are having.

Do not mix ondansetron oral solution with anything (not even water) before swallowing it.

To prevent nausea and vomiting from chemotherapy or radiotherapy

On the day of chemotherapy or radiotherapy

- the usual adult dose is 8 mg taken one to two hours before treatment and another 8 mg twelve hours after.

On the following days

- the usual adult dose is two 5 ml spoonfuls 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. Look at the label for more information.

- the usual dose for a child is up to one 5 ml

- spoonful 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 four 5 ml spoonfuls before your operation.

Children aged over 1 month and adolescents: It is recommended that ondansetron oral solution is given as an injection.

Patients with moderate or severe liver problems

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

Ondansetron oral solution should start to work within one or two hours of taking a dose.

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 than the label says.

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 oral solution 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 (as shown on the label)
- 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 shown on the label
- do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of ondansetron oral solution, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, ondansetron oral solution can cause side effects, although not everybody gets them.

Allergic reactions

If you have an allergic reaction, stop taking it and see a doctor straight away. 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.

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 heart beat
- 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.

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.

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5. How to store ondansetron oral solution

Keep out of the sight and reach of children.

Do not use ondansetron oral solution after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Use within 28 days after first opening
Do not refrigerate.

Keep the bottle in the outer carton 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 oral solution contains

The active substance is ondansetron. Each 5ml ondansetron oral solution contains 4mg of ondansetron (as hydrochloride dihydrate).

The other ingredients are sorbitol solution (non-crystallising) (E420), sodium benzoate (E211), sodium citrate (E331), citric acid (for pH adjustment) (E330), strawberry flavour (contains ethanol, furaneol, benzyl alcohol, propylene glycol and butyl hydroxyl anisole) and purified water.

What ondansetron oral solution looks like and contents of the pack

Ondansetron oral solution is a clear, colourless, strawberry flavoured solution.

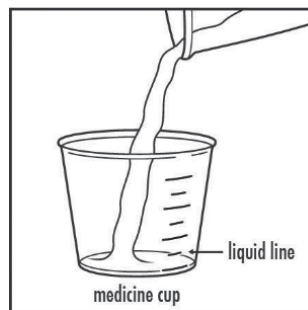
Amber coloured glass bottles (Type-III) with a tamper-evident child resistant caps (constructed of a white HDPE outer, translucent polypropylene inner and LDPE tamper band) and wad.

The bottles contain 50ml of ondansetron oral solution.

A 20ml dosing cup (graduated at 2.5ml, 5ml, 10ml, 15ml and 20ml) and a 5ml oral syringe (graduated at 0.25ml) with a bottle adaptor are provided.

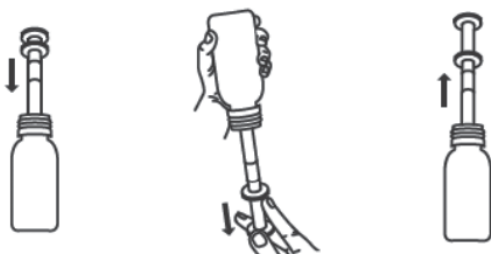
Using the dosing cup:

1. Place the dosing cup on a flat surface so that when poured, the dose is correct. Holding the cup tipped or at an angle can make you measure the wrong amount.
2. Unscrew the bottle cap and pour the oral solution into the dosing cup.
3. Use the numbers and liquid lines on the side of the cup to pour the correct dose, as instructed by your doctor or pharmacist.
4. Drink the oral solution from the dosing cup
5. After use, replace the bottle cap. Wash the dosing cup in warm water and allow to dry. Store out of reach of children.



Using the oral syringe:

1. When you use this medicine for the first time, place the adaptor in the neck of the bottle.
2. Push the syringe firmly into the adaptor in the neck of the bottle.
3. 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 corrected mark on the syringe. Your doctor will tell you the right dose for you or your child.
4. Turn the bottle the right way up, removing the syringe from the adaptor by gently twisting the syringe.



5. 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
6. Repeat steps 2-5, as necessary, to give the full dose.
7. After use, replace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of reach of children.

Marketing Authorisation Holder

Somex Pharma
Ilford, Essex, IG3 8BS. UK.

Manufacturer

Kleva Pharmaceuticals SA
189 Parnithos Avenue, 136 75 Acharnai, Athens, Greece.

Other sources of information

To request a copy of this leaflet in braille or large print, please call 020 8590 9399 (UK Only).

This leaflet was last revised in 09/2022.