**Package leaflet: Information for the user**
**Ondansetron 4mg/5ml Syrup**

**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, 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 you get any side effects, talk to 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 Syrup but it will be referred as Ondansetron throughout this leaflet.

**What is in this leaflet**



## 1. What Ondansetron is and what it is used for

Ondansetron contains the active substance ondansetron hydrochloride dihydrate. This belongs to a group of medicines called anti-emetics.

Ondansetron is used for:
- preventing nausea and vomiting caused by chemotherapy or radiotherapy for cancer in **adults**
- preventing nausea and vomiting after surgery in **adults**
- preventing nausea and vomiting caused by chemotherapy for cancer in **children and adolescents** aged 6 months to 17 years

Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.
Ondansetron should start to work within one or two hours of taking a dose. You must talk to a doctor if you do not feel better or if you feel worse.

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

**Do not take Ondansetron if:**
- you are taking apomorphine (used to treat Parkinson's Disease)
- you are allergic (hypersensitive) to Ondansetron or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

If you are not sure, talk to your doctor, nurse or pharmacist before taking Ondansetron.

**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)
- you have an uneven heart beat (arrhythmias)
- you are allergic to medicines similar to ondansetron, such as granisetron (known as 'Kytril')
- you have liver problems
- you have a blockage in your gut or suffer from severe constipation
- you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium
- you are intolerant to some sugars.

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

**Children**
Do **not** give this medicine to children **under 6 months of age**

**Other medicines and Ondansetron**
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Ondansetron can affect the way some medicines work. Also some medicines can affect the way Ondansetron 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, as these medicines may reduce the effect of Ondansetron
- rifampicin used to treat infections such as tuberculosis (TB), as this medicine may reduce the effect of Ondansetron
- antibiotics such as erythromycin or ketoconazole
- anti-arrhythmic medicines used to treat an uneven heart beat, as these medicines may interact with Ondansetron & effect the rhythm of the heart
- beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines, as these medicines may interact with ondansetron and effect the rhythm of the heart
- tramadol, a pain killer, as Ondansetron may reduce the effect of tramadol
- medicines that affect the heart (such as haloperidol or methadone)
- cancer medicines (especially anthracyclines), as these may interact with ondansetron to cause heart arrhythmias
- medicines used to treat depression and/or anxiety:
    - SSRIs (selective serotonin reuptake inhibitors) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
    - SNRIs (serotonin noradrenaline reuptake inhibitors) 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.

**Pregnancy, breast-feeding and fertility**
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 the mother's milk. Ask your doctor or midwife for advice.

**Driving and using machines**
It is not expected that Ondansetron will affect your ability to drive; however, if any of the side effects (listed section 4) affect you (e.g. dizziness, blurred vision) caution is advisable. **Do not drive or operate machines if you are feeling unwell.**

**Ondansetron contains:**

Sorbitol (E420): This medicine contains 2100mg sorbitol in each 5ml dose which is equivalent to 420mg/ml. 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 benzoate (E211): This medicine contains 6mg sodium benzoate in each 5ml dose which is equivalent to 1.2mg/ml.
Propylene glycol (E1520): This medicine contains 14.1mg/5ml propylene glycol in each 5ml dose which is equivalent to 2.8mg/ml.
Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 5ml dose, that is to say essentially 'sodium-free'.

## 3. How to take Ondansetron

Always take this medicine exactly as your doctor has told you. 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 with anything (not even water) before swallowing it.

**Doses**
The recommended dose is:

**To prevent nausea and vomiting from chemotherapy or radiotherapy**
**Adults:**
On the day of chemotherapy or radiotherapy:
- the usual adult dose is 8mg (two 5 ml spoonfuls, large end of spoon supplied in pack) taken one to two hours before treatment and another 8mg (10ml) twelve hours after**.**

On the following days:
- the usual adult dose is 8mg (two 5 ml spoonfuls, large end of spoon supplied in pack) twice a day
- this may be given for up to 5 days.

If your chemotherapy or radiotherapy is likely to cause severe nausea and vomiting, you may be given more than the usual dose of Ondansetron. Your doctor will decide this.

**Children and Adolescents (6 months to 17 years):**
**To prevent nausea and vomiting from chemotherapy only:**
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 4mg (one 5 ml spoonful, large end of spoon supplied in pack) twice a day
- this can be given for up to 5 days.

**Infants under 6 months of age:**
Ondansetron is not recommended in infants under 6 months of age for the prevention of nausea and vomiting from chemotherapy.

**To prevent nausea and vomiting after an operation**
**Adults:**
The usual adult dose is 16mg (four 5 ml spoonfuls, large end of spoon supplied in pack) given an hour before your operation.

**Children and Adolescents (aged 1 month to 17 years):**
**Children aged 2 years and over**
It is recommended that Ondansetron is given as an injection.

**Children aged under 2 years**
There is little information on the correct dose of Ondansetron for the treatment of nausea & vomiting after an operation in children under 2 years of age. The doctor will decide the correct dose.

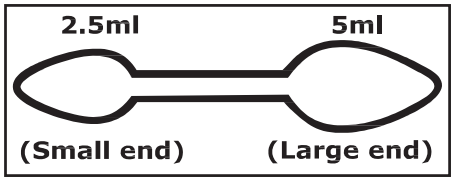
**Patients with moderate or severe liver problems**
The total daily dose should not be more than 8mg (two 5 ml spoonfuls, large end of spoon supplied in pack). If you have blood tests to check how your liver is working, this medicine may affect the results.

**If you are sick (vomit) within one hour of taking a dose:**
- take the same dose again
- otherwise, do not take more Ondansetron than recommended.

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

**Method of administration:**
- use the 2.5-5ml double-ended spoon supplied in the pack (see below) to measure the required dose
- swallow the solution
- wash the spoon with clean water after taking every dose
- once measured, the solution should be consumed within 3 hours.

**Double-ended Spoon**




**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 it as soon as you remember.
- However, if it is nearly time for the next dose, skip the missed dose.
- do not take a double dose to make up for a forgotten dose.

If you forget a dose but do not feel sick:
- take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- do not take a double dose to make up for a forgotten dose.
- Important: A minimum time interval of 12 hours must be allowed between doses.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

## 4. Possible side effects

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

**Allergic reactions**
These reactions are rare in people taking Ondansetron. 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 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
- slow heart rate
- fits
- unusual body movements or shaking.

**Rare (may affect up to 1 in 1,000 people)**
- feeling dizzy or lightheaded during IV administration
- blurred vision
- disturbance 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)
- poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.

**Frequency unknown**

Myocardial ischemia

Signs include:

- sudden chest pain or
- chest tightness

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

**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 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 carton and bottle after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Discard 60 days after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- 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 contains**

The active substance is ondansetron.

Each 5ml syrup contains 4mg ondansetron (as ondansetron hydrochloride dihydrate).

The other ingredients are citric acid monohydrate (E330), sodium citrate (E331), sorbitol, liquid (non crystallising) (E420), sodium benzoate (E211), strawberry flavour (contains propylene glycol (E1520)) and purified water.

**What Ondansetron looks like and contents of the pack**

Ondansetron is a clear, colourless syrup with a strawberry flavour. It is supplied in type III amber colour glass bottle with HDPE, EPE wadded, tamper evident, child resistant screw on white plastic polypropylene cap.

The pack also contains a plastic double ended spoon with the smaller end measuring 2.5ml and the larger end measuring 5ml.

Ondansetron is supplied in bottles containing 50ml, 100ml and 300ml syrup.

Not all pack sizes may be marketed.

**POM**

**Marketing Authorisation Holder:**
Syri Pharma Limited t/a Thame Laboratories
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**Manufacturer:**
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OR

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OR

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OR

Pharmadox Healthcare Ltd.,
KW20A Kordin Industrial Park,
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**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**
IE, UK (NI): Ondansetron 4mg/5ml Syrup
NL: Ondansetron 4 mg/5 ml Focus Care, Stroop

This leaflet was last revised in 10/2023.