

Syfran 4mg / 5mL Syrup

Consumer Medication Information Leaflet (RiMUP)

Ondansetron (as ondansetron hydrochloride dihydrate) (4mg / 5mL)

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What Syfran is used for

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

How Syfran works

Syfran 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.

Syfran 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.

Before you use Syfran

-When you must not use it

Do not take Syfran 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 List of Excipients). 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 Syfran.

-Before you start use it

Talk to your doctor or pharmacist before taking Syfran 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 Syfran.

Children

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

-Taking other medicines

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 Syfran can affect the way some medicines work. Also some medicines can affect the way Syfran 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 Syfran.
- rifampicin used to treat infections such as tuberculosis (TB), as this medicine may reduce the effect of Syfran.
- antibiotics such as erythromycin or ketoconazole
- anti-arrhythmic medicines used to treat an uneven heartbeat, as these medicines may interact with Syfran and affect 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 affect the rhythm of the heart

- tramadol, a pain killer, as Syfran 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 Syfran.

Excipients:

- Sorbitol: 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: This medicine contains 6mg sodium benzoate in each 5ml dose which is equivalent to 1.2mg/ml.
- Propylene glycol: 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'.

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How to use Syfran

-How much to use

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 Syfran Syrup. Your doctor will decide on 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:

Syfran Syrup 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 6 month to 17 years):

Children aged 2 years and over

It is recommended that Syfran is given as an injection.

Children aged under 2 years

There is little information on the correct dose of Syfran for the treatment of nausea and 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:

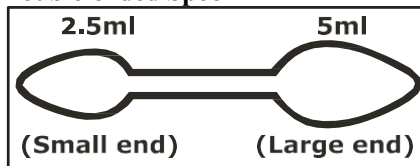
- take the same dose again
- otherwise, do not take more Syfran than recommended.

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



-When to use it

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 Syfran with anything (not even water) before swallowing it.

-How long to use it

Continue taking Syfran Syrup for as long as your doctor recommends.

-If you forget to use it

If you forget a dose and feel sick and 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 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.

-If you use too much (overdose)

If you or your child take more Syfran than you should, contact your doctor or go to the hospital straight away. Take the medicine pack with you.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

-Things you must not do

Do not stop taking the medicine unless your doctor tells you to.
Do not take any new medicines without consulting your doctor.
Do not give Syfran to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Pregnancy, breast-feeding and fertility
Only use Syfran 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 Syfran 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

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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 Syfran.

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

Do not breast-feed if you are taking Syfran. 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 Syfran will affect your ability to drive; however, if any of the side effects affect you (e.g. dizziness, blurred vision) caution is advisable. Do not drive or operate machines if you are feeling unwell.

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 Syfran. 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 Syfran 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
- slow heart rate
- fits
- unusual body movements or shaking.

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

- feeling dizzy or light headed 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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Syfran Syrup

-Storage

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 outer carton after EXP. The expiry date refers

to the last day of that month.

Store below 30°C.

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.

-Disposal

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.

Product Descriptions

-What it looks like

Syfran 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.

-Ingredients

Active ingredient:

Ondansetron (as ondansetron dihydrochloride dihydrate)

Inactive ingredients:

Citric acid monohydrate, sodium citrate, sorbitol liquid (non crystallizing), sodium benzoate, strawberry flavour (contains propylene glycol) and purified water.

-MAL number

MALXXXXXXXX

-Pack Size

50mL

Manufacturer

Syri Limited
Unit 4, Bradfield Road, Ruislip,
HA4 0NU, United Kingdom

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Product Registration Holder

Handsome Global Pharmacare Sdn.
Bhd.
15-7, Infinity Tower,
Jalan SS6/3, Kelana Jaya,
47301, Petaling Jaya, Selangor.

Date of revision

15/11/2025

Serial number

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