

Package Leaflet: Information for the User
Zotron 4mg/2ml (ή 8mg/4ml) Solution for Injection or Infusion
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 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 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:

- 1 What Zotron injection is and what it is used for
- 2 What you need to know before you have Zotron injection
- 3 How to have Zotron injection
- 4 Possible side effects
- 5 How to store Zotron injection
- 6 Contents of the pack and other information

1. What Zotron injection is and what it is used for

Zotron injection contains a medicine called ondansetron. This belongs to a group of medicines called anti-emetics.

Zotron injection 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.

Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.

2. What you need to know before you have Zotron injection

Do not have Zotron injection if:

- you are taking apomorphine (used to treat Parkinson's disease)
- you are allergic (hypersensitive) to ondansetron or any of the other ingredients in Zotron injection (listed in Section 6).

If you are not sure, talk to your doctor, nurse or pharmacist before having Zotron injection.

Warnings and precautions

Check with your doctor, nurse or pharmacist before having Zotron injection 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 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 having Zotron injection.

Other medicines and Zotron

Please tell your doctor, nurse or pharmacist if you are taking, or have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Zotron can affect the way some medicines work. Also some other medicines can affect the way Zotron 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 Zotron injection.

Zotron injection should not be given in the same syringe or infusion (drip) as any other medication.

Pregnancy and breast-feeding

It is not known if Zotron is safe during pregnancy. If you are pregnant, think you are pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before having Zotron injection.

Do not breast-feed if you have Zotron. 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 Zotron injection

This medicine contains sodium citrate and sodium chloride. This means that Zotron injection contains 7 mg of sodium per 4 mg dose, which is less than 1 mmol sodium (23 mg) per dose i.e.

Essentially "sodium-free".

3 How to have Zotron injection

Zotron injection is normally given by a nurse or doctor. The dose you have been prescribed will depend on the treatment you are having.

To prevent nausea and vomiting from chemotherapy or radiotherapy in adults

On the day of chemotherapy or radiotherapy

- the usual adult dose is 8 mg given by a slow injection into your vein or muscle, just before your treatment, and another 8 mg twelve hours later. After chemotherapy, your medicine will usually be given by mouth as an 8 mg Zotron tablet or 10 ml (8 mg) Zotron syrup.

On the following days

- the usual adult dose is one 8 mg tablet or 10 ml (8 mg) syrup taken 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 Zotron. Your doctor will decide this.

To prevent nausea and vomiting from chemotherapy in 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

On the day of chemotherapy

- the first dose is given by an injection into the vein, just before your child's treatment. After chemotherapy, your child's medicine will usually be given by mouth twelve hours later, as Zotron syrup or a Zotron tablet.

On the following days

- 2.5 ml (2 mg) syrup twice a day for small children and those weighing 10 kg or less
- one 4 mg tablet or 5 ml (4 mg) syrup twice a day for larger children and those weighing more than 10 kg
- two 4 mg tablets or 10 ml (8 mg) syrup twice a day for teenagers (or those with a large body surface area)
- these doses can be given for up to five days

To prevent and treat nausea and vomiting after an operation

Adult:

- The usual dose for adults is 4 mg given by a slow injection into your vein or an injection into your muscle. For prevention, this will be given just before your operation.

Children:

- For children aged over 1 month and adolescents the doctor will decide the dose. The maximum dose is 4 mg given as a slow injection into the vein. For prevention, this will be given just before the operation.

Patients with moderate or severe liver problems

The total daily dose should not be more than 8 mg.

If you keep feeling or being sick

Zotron injection should start to work soon after having the injection. If you continue to be sick or feel sick, tell your doctor or nurse.

If you have more Zotron injection than you should

Your doctor or nurse will give you or your child Zotron injection so it is unlikely that you or your child will receive too much. If you think you or your child have been given too much or have missed a dose, tell your doctor or nurse.

4 . Possible side effects

Like all medicines, Zotron injection can cause side effects, although not everybody gets them.

Allergic reactions

If you have an allergic reaction, tell your doctor or a member of the medical staff 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 have Zotron injection with a medicine called cisplatin, otherwise this side effect is uncommon)
- irritation and redness at the site of injection.

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 Pharmaceuticals Services

Ministry of Health

CY-1475, Nicosia

www.moh.gov.cy/phs

By reporting side effects you can help provide more information on the safety of this medicine.

5 . How to store Zotron injection

- Keep this medicine out of the sight and reach of children.
- Do not use Zotron injection after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.
- Store Zotron injection below 30°C. Protect from light.
- When Zotron injection is diluted in intravenous fluids:
 - it must be stored at 2-8°C for not more than 24 hours
 - it does not need to be protected from light during infusion.
- 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 Zotron injection contains

- The active ingredient is ondansetron. Each 2 ml Zotron injection ampoule contains ondansetron 4 mg. Each 4 ml Zotron injection ampoule contains ondansetron 8 mg.
- The other ingredients are sodium chloride, citric acid monohydrate, sodium citrate and Water for Injections.

What Zotron injection looks like and contents of the pack

Zotron injection is a clear, colourless liquid.

Zotron injection is available in ampoules type I

Packed in boxes of 5 ampoules.

Marketing Authorisation Holder and Manufacturer

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