



Ondansetron Injection USP 4mg/2ml, 8mg/4ml, 40mg/20ml

Package leaflet: information for the user

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

- Keep this leaflet. You may want to read it again.
- If you have any further questions, ask your doctor 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Ondansetron Injection is and what it is used for
2. What you need to know before you are given your Ondansetron Injection
3. How your Ondansetron Injection is given to you
4. Possible side effects
5. How to store your Ondansetron Injection
6. Contents of the pack and other information.

The name of your medicine is Ondansetron 2mg/ml Solution for Injection (referred to as Ondansetron Injection throughout this leaflet).

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

Your medicine comes as a solution for injection or infusion (drip). The active ingredient is ondansetron. The other ingredients are listed in section 6. Ondansetron belongs to a group of medicines called anti-emetics or anti-sickness medicine. Ondansetron can be used to prevent or treat nausea (feeling sick) or vomiting, following an operation, cancer chemotherapy or radiation treatment. Ask your doctor, nurse or pharmacist if you would like any further explanation about these uses.

2. What you need to know before you are given your

Ondansetron Injection

You should not be given this

injection if:

- You have ever had an allergic or unusual reaction to Ondansetron or any of the other ingredients of this medicine (listed in section 6), or to medicinal products from the same class (e.g. granisetron, dolasetron).
- You are taking apomorphine (used to treat Parkinson's disease).

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

Warnings and precautions

Talk to your doctor or pharmacist before receiving Ondansetron Injection

- if you have or have had prolonged QT interval (seen on an ECG, electrical recording of the heart),
- if you have or have had alterations in heart rhythm (including a slow heart beat) or other heart problems (such as heart failure or conduction disorders) or,
- if you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium or,
- if you have liver problems or,
- if you have gut problems such as a blockage or suffer from severe constipation or,
- if you have just had or are going to have your adenoids or tonsils removed.

Special precautions should be taken if Ondansetron Injection is to be given to a child receiving medication for cancer treatment which might alter liver function.

Other medicines and Ondansetron Injection

Please tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines and especially any of the following medicines:

- * Phenytoin, carbamazepine; to treat epilepsy,
- * Antibiotics such as rifampicin or erythromycin,
- * Ketoconazole, a medicine used to treat a fungal infection,
- * Tramadol, a strong painkiller,

- * Medicines used to treat an uneven heart beat (arrhythmias),
- * Cancer medicines (e.g. anthracyclines or trastuzumab), antibiotics (e.g. erythromycin), antifungals (e.g. ketoconazole) or other medicines which might disturb your heart rhythm,
- * Beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines,
- * Medicines to treat depression such as SSRIs (selective serotonin reuptake inhibitors) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, or SNRIs (serotonin and noradrenaline reuptake inhibitors) including venlafaxine, duloxetine, as these 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.

You should not be given this medicine if you are already taking apomorphine (used to treat Parkinson's disease); because severe hypotension (low blood pressure) and loss of consciousness have been reported in patients treated with both apomorphine and Ondansetron Injection at the same time.

Pregnancy and breast-feeding

You should not use Ondansetron Injection 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 Injection.

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

Do not breast-feed if you are being treated with Ondansetron Injection. This is because small amounts pass into the mother's breast milk. Ask your doctor or midwife for advice.

Driving and using machines

Ondansetron Injection should not affect your ability to drive or use machines.

Ondansetron Injection contains sodium

This medicinal product contains 3.6 mg sodium per ml of solution for injection. To be taken into consideration by patients on a controlled sodium diet.

3. How your Ondansetron Injection is given to you

Ondansetron Solution for Injection will usually be given to you by a nurse or doctor by slow injection or infusion (drip) into a vein (intravenously).

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, 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 tablet or 8 mg Ondansetron syrup.

On the following days

- The usual adult dose is one 8 mg tablet or 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 ondansetron. 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. 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

Ondansetron syrup or an Ondansetron tablet.

On the following days

- 2 mg syrup twice a day for small children and those weighing 10 kg or less
- one 4 mg tablet or 4 mg syrup twice a day for larger children and those weighing more than 10 kg
- two 4 mg tablets or 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. 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.

Ondansetron Injection should start to work soon after you

are given the injection. If you continue to be sick or feel sick, tell your doctor or nurse.

If you are concerned about how much medicine you have been given or how often you have been given it, please tell your doctor or nurse.

If you have more Ondansetron Injection than you should

There is limited experience of ondansetron overdose. In a few patients, the following symptoms were observed: visual disturbances, severe constipation, low blood pressure and unconsciousness. In all cases, the symptoms disappeared completely. Tell your doctor if any of these symptoms occur.

Your doctor or nurse will give you or your child Ondansetron 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, this medicine can cause side effects, although not everybody gets them. Tell your doctor or a member of the medical staff straight away if you have:

- An allergic reaction. 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. If you are allergic to similar medicine you are more likely to suffer these effects.

- Fits (seizures)
- Disturbances in heart rhythm (sometimes causing a sudden loss of consciousness).

Other side effects include:

Very Common side effects (may affect more than 1 in 10 people)

- Headache.

Common side effects (may affect up to 1 in 10 people)

- Constipation. If you are constipated tell your doctor,
- Feeling flushed or warm,
- Redness or irritation at the injection site.
- Changes to liver function test results (if you are given Ondansetron Injection with a medicine called cisplatin, otherwise this side effect is uncommon).

Uncommon side effects (may affect up to 1 in 100 people)

- Spasms in the muscles of the face and eyes, tremor, uncontrollable movements,
- Hiccups,
- Chest pain, an irregular or slow heartbeat or low blood pressure.

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

- Blurred vision,
- Dizziness when ondansetron is injected quickly into the vein.

Very rare side effects (may affect up to 1 in 10,000 people)

- Temporary loss of eyesight, which usually comes back within 20 minutes. Side effects in children and adolescents were comparable to that seen in adults.

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.

5. How to store Ondansetron Injection

- Keep this medicine out of the sight and reach of children.
- Do not store the injection above 30°C.
- Store in the original package. Protect from light.
- Do not use this medicine after the expiry date which is stated on the ampoule and carton.

6. Contents of the pack and other information What



Ondansetron Injection contains

The active substance is: ondansetron (as ondansetron hydrochloride dihydrate). Each ml of solution contains 2 mg of ondansetron.

Each 2 ml ampoule contains 4 mg of ondansetron.

Each 4 ml ampoule contains 8 mg of ondansetron.

The other ingredients are: citric acid monohydrate, sodium citrate, sodium chloride and water for injections.

What Ondansetron Injection looks like and contents of the pack

Ondansetron Solution for Injection or Infusion is a clear solution (liquid) and is supplied in 2ml (4mg) and 4ml (8mg) amber glass ampoules.

7.Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

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