For The Use of A Registered Medical Practitioner or A Hospital or A Laboratory

Ondansetron Injection IP

Composition :

Each ml contains :

Ondansetron Hydrochloride	IP	
equivalent to Ondansetron		2 mg
Water for Injection	IP	q.s.

AMERICAN
ONDICAN 2
Injection

For IM/IV Use Only

1. WHAT ONDANSETRON 2 mg/ml IS AND WHAT IT IS USED FOR

Ondansetron 2 mg/ml belongs to a group of medicines called anti-emetics, drugs against feeling sick or being sick. Some medical treatment with medicines for treatment of cancer (chemotherapy) or radiotherapy can make you feel sick or be sick. Also after surgical treatment you can feel sick or be sick. Ondansetron 2 mg/ ml may help to reduce these effects.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ONDANSETRON 2 mg/ml Do not use Ondansetron 2 mg/ml: if you are allergic (hypersensitive) to ondansetron, any of the other ingredients of Ondansetron 2 mg/ml or to medicinal products from the same class (e.g. granisetron or dolasetron).
if you are taking apomorphine (a medicine used to treat Parkinson's disease).Warnings and precautions Talk to your doctor or pharmacist before using Ondansetron 2 mg/ml if you are hypersensitive to other medicines against feeling sick or being sick.if you have a blockage in your gut or suffer from severe constipation. Ondansetron can enhance the blockage or constipation.if you have cardiac problems (e.g. congestive heart failure which causes shortness of breath and swollen ankles).you have an uneven heart beat (arrhythmias).if you are having your tonsils out.if your liver is not working as well as it should.you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.Other medicines and Ondansetron 2 mg/ml.Tell your doctor 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.Tell your doctor or pharmacist if you are taking any of the following medicines:phenytoin or carbamazepine used to treat epilepsy rifampicin used to treat infections such as tuberculosis (TB) tramadol, a pain killer antibiotics such as erythromycin or ketoconazole, anti-arrhythmic medicines used to treat an uneven heart beat,Beta - blocker used to treat certain heart or eye problems, anxiety or prevent migraines medicines that affect the heart (such as haloperidol or methadone), 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, anthracylines (cancer medicine) Ondansetron changes the effect of some drugs and vice versa. This includes: apomorphine (a medicine used to treat Parkinson's disease): a significant drop in blood pressure and loss of consciousness has been reported with concomitant use of ondansetron and apomorphine.tramadol (a painkiller): ondansetron may reduce the analgesic effect of tramadol.phenytoin, carbamazepine (anti-epileptics) and rifampicin (an antibiotic): the blood concentrations of ondansetron are decreased.Pregnancy and breast-feedingOnly use Ondansetron 2 mg/ml 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 2 mg/ml 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 2 mg/ml. If you are a woman of childbearing potential you may be advised to use effective contraception.Ondansetron passes into mother's milk. Therefore mothers receiving ondansetron should NOT breast-feed.Driving and using machines Ondansetron has no or negligible effect on the ability to drive or use machines.Ondansetron 2 mg/ml contains sodiumThis medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. HOW TO USE ONDANSETRON 2 mg.ml Method of administration Ondansetron 2 mg/ml is given as intravenous injection (into a vein) or, after dilution, as intravenous infusion (for a longer time). It will usually be given by a doctor or a nurse.Dosage : Your doctor will decide on the correct dose of ondansetron therapy for you. The dose varies depending on your medicinal treatment (chemotherapy or surgery), on your liver function and on whether it is given by injection or infusion. In case of chemotherapy or radiotherapy the usual dose in adults is 8 - 32 mg ondansetron a day. For treatment of post-operative nausea and vomiting a single dose of 4 mg ondansetron is usually given.

Use in children and adolescents Children aged over 6 months and adolescents The doctor will decide the dose. In cases of chemotherapy or radiotherapy the usual dose in children and adolescents is 4 mg.Children aged over 1 month and adolescents The doctor will decide the dose. For treatment of post-operative nausea and vomiting a maximum dose of 4 mg is given into a vein. Dosage adjustment
Patients with hepatic impairment:In patients having hepatic problems the dose has to be adjusted to a maximum daily dose of 8 mg ondansetron..Elderly: There is limited experience in the use of ondansetron in the prevention and treatment of post-operative nausea and vomiting (PONV) in the elderly, however ondansetron is well tolerated in patients over 65 years receiving chemotherapy.
Patients with renal impairment or poor sparteine/debrisoquine metabolism: No alteration of daily dosage or frequency of dosing or route of administration is required. Duration of treatment Your doctor will decide on the duration of ondansetron therapy for you. After intravenous administration of Ondansetron 2 mg/ml the therapy may be continued with other dosage forms.
If you use more Ondansetron 2 mg/ml than you should Little is known at present about overdosage with ondansetron. In a few patients, the following effects were observed after overdose: visual disturbances, severe constipation, low blood pressure and unconsciousness. In all cases, the symptoms disappeared completely. There is no specific antidote to ondansetron; for that reason, if overdose is suspected, only the symptoms should be treated.Tell your doctor if any of these symptoms occur.

Your doctor or nurse will give you or your child Ondansetron 2 mg/ml 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. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS Like all medicines, this medicine can cause side effects, although not everybody gets them.Uncommon (may affect up to 1 in 100 people): Chest pain, cardiac arrhythmias (changes in the way your heart beats) and bradycardia (slow heart rate). Chest pain and cardiac arrhythmias may be fatal in individual cases. Rare (may affect up to 1 in 1,000 people):Immediate allergic (hypersensitivity) reactions (reaction in which the body reacts with an exaggerated immune response to a foreign agent), including life-threatening allergic reaction. These reactions may be: swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing. Additionally rash or itching and hives.Altered hypersensitivity reactions were also observed in patients, who were sensitive to medicinal products from the same class.Inform your doctor immediately if you experience any symptoms suggestive of an allergic reaction. Very Common (may affect more than 1 in 10 people):Headache.Common (may affect up to 1 in 10 people):Sensations of flushing or warmth.Ondansetron is known to increase the large bowel transit time and may cause constipation in some patients. Local reactions at the IV injection site.Uncommon (may affect up to 1 in 100 people):Involuntary movement disorders, e.g. spasmodic movement of eyeballs, abnormal muscle contractions that may cause twisting or jerking movements of the body, seizures (e.g. epileptic spasms).Hypotension (low blood pressure).Hiccups.Asymptomatic increases of liver function. These reactions were particularly observed in patients under chemotherapy with cisplatin.Hypersensitivity reactions around the injection site (e.g. rash, urticaria, itching) may occur, sometimes extending along the drug administration vein.Rare (may affect up to 1 in 1,000 people):Transitory changes in the electrocardiogram (ECG) predominantly after intravenous application of ondansetron. QTc prolongation (including Torsades de Pointes) Dizziness during rapid intravenous administration.
Transient visual disturbances (e.g. blurred vision) during rapid intravenous administration. Very rare (may affect up to 1 in 10,000 people):Depression. In individual cases transitory blindness was reported in patients receiving chemotherapeutic agents including cisplatin. Most reported cases resolved within 20 minutes. Some cases of transient blindness were reported as cortical in origin. If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE ONDANSETRON 2 mg/ml 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 ampoule label and carton. The expiry date refers to the last day of that month. Keep the ampoules in the outer carton, in order 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 2 mg/ml contains The active substance is ondansetron. Each ampoule with 2 ml contains 4 mg ondansetron. Each millilitre contains 2 mg ondansetron as ondansetron hydrochloride dihydrate.

The other ingredients are:

Methly Paraben, Propyl Paraben and Water for injection.What Ondansetron 2 mg/ml looks like and contents of the pack Ondansetron 2 mg/ml is a clear and colourless solution in colourless glass ampoules containing 2 ml of solution for injection.

Pack sizes: 10 ampoules

Storage : Store protected from light,at a temperature not exceeding 30ºC.

Keep the medicine out of reach of children.

Do not use if solution in not clear or has suspended matter.

Dosage : As directed by the Physician.

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