PACKAGE LEAFLET: Information for the patient

ONDANSETRON

Solution for injection – 8 mg / 4 ml

(Ondansetron hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ondansetron is and what it is used for
2. Before you take Ondansetron
3. How to take Ondansetron
4. Possible side effects
5. How to store Ondansetron
6. Further information

1. WHAT ONDANSETRON IS AND WHAT IT IS USED FOR

Ondansetron contains the active substance ondansetron hydrochloride dihydrate.

Ondansetron is a selective antagonist of 5-hydroxytryptamine receptors-3 (5-HT3) and belongs to a group of medicines called antiemetics.

Ondansetron is used:

- in the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy;
- in the treatment and prevention of post-operative nausea and vomiting.

Your doctor may have given Ondansetron for a different purpose. Ask your doctor if you want to know why you were given this medicine.

2. BEFORE YOU TAKE ONDANSETRON

Do not take Ondansetron if:

- you are allergic to ondansetron or to any of the inactive ingredients mentioned at the end of this leaflet (see section 6);
- you are taking apomorphine (medicine to treat Parkinson disease).

Take special care with Ondansetron

Ask your doctor before taking Ondansetron.

It should be used with caution in patients:

- with congenital prolonged QT interval syndrome, congestive heart failure, bradyarrhythmias, electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), or in those who are taking drugs that may prolong QT interval, because all of these lead to additional prolongation of QT interval;
- after abdominal surgery or in chemotherapy-induced nausea and vomiting, because it may mask progressive ileus and gastric distention;
- who are allergic to medicines similar with ondansetron;
- who will be subject of an adenotonsillar surgery (removal of tonsils), because ondansetron may mask occult bleeding;
- with moderate or severe hepatic impairment;
- who are following a controlled sodium diet; this medicinal product contains about 1.25 mmol (28.8 mg) sodium in 16 mg (2 ampoules);
- who are pregnant or breastfeeding.

Taking other medicines

Inform your doctor or pharmacist if you are taking, have recently taken or might take other medicines, even those without a prescription.

It is particularly important to inform your doctor if you are being treated with:

- potent inducers of hepatic isoenzyme CYP3A4 (such as phenytoin, carbamazepine, and

rifampicin), which increase ondansetron clearance and reduce its plasma concentrations;

- apomorphine, because co-administration with ondansetron causes profound hypotension and loss of consciousness, hence, concomitant use of ondansetron with apomorphine is contraindicated;
- analgesics such as tramadol, whose effect is reduced by ondansetron;
- anti-arrhythmic medicines used to treat an uneven heartbeat;
- beta-blockers;
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram and SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression or anxiety including venlafaxine, duloxetine;
- some medicines to treat cancer (especially anthracyclines and trastuzumab);
- other drugs which prolong QT interval.

Taking Ondansetron with food and drinks

Food and drinks do not affect the absorption of ondansetron.

Pregnancy

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.

Breastfeeding

Tell your doctor or pharmacist if you feed your baby with breastmilk.

Studies in animals have shown that ondansetron passes into breastmilk, so mothers who are taking Ondansetron should be recommended not to breast-feed their baby.

Driving and using machines

No data exist about the impact of the use of ondansetron in the ability of driving and using machinery. During rapid intravenous injection, rare cases of transient visual disturbances such as blurred vision (or very rarely transient blindness) have been reported.

Important information about some of the ingredients of Ondansetron

This drug contains about 1.25 mmol (28.8 mg) sodium in 16 mg (2 ampoules). It should be considered in patients who are following a controlled diet with salt.

3. HOW TO TAKE ONDANSETRON

Ondansetron injection is administered by a nurse or doctor. The dose that you will be prescribed will depend on the treatment you will have.

Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy

Adults

- the single dose should not exceed 16 mg
- the usual dose is 8 mg *by injection into the muscle* or *slow injection into a vein* immediately before treatment, and extended if necessary with two other doses of 8 mg at intervals of 4 hours
- afterwards, it is continued with medication by mouth 8 mg every 12 hours up to 5 days.

Elderly

If you are over 65, your doctor will adjust the dosage according your needs.

Prevention and treatment of postoperative nausea and vomiting

The usual dose for adults is 4 mg *injected into the muscle* or *slow injection into a vein*. For prevention, it is given immediately before surgery (during induction of anesthesia).

Use and dosage in children should be justified by the doctor.

Patients with hepatic impairment

In patients with moderate or severe hepatic impairment, it is recommended that the total daily dose of ondansetron should not exceed 8 mg.

If you take more Ondansetron than you should

This medicine will be administered by a specialized medical personnel so it is unlikely that overdose occurs, however inform your doctor if you think you have taken a higher dose than you should.

Little is known at present about overdosage with ondansetron.

A limited number of patients have experienced overdoses with ondansetron, the usual symptoms being: fever, rash, pruritus, restlessness, CNS depression, self-limited seizures, tachycardia, mild elevations of liver enzymes, hypotension, temporary blindness (2 to 3 minutes duration).

There is no specific antidote for the overdose of ondansetron, therefore in all suspected cases, symptomatic and supportive treatment should be done.

If you forget to take Ondansetron

This medicine will be administered by a specialized medical personnel, so it is unlikely that a dose will be forgotten, however, it should not be taken a double dose to make up for the forgotten dose.

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Immune system disorders: there have been rare reports of immediate hypersensitivity reactions, including anaphylaxis.

If you have an allergic reaction, talk to your doctor or nurse immediately.

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);
- collapse.

Myocardial ischemia

Signs include:

- sudden chest pain or,
- chest tightness.

Very common / common side effects

Headache, constipation, a sensation of reddening and warmth, hypersensitivity reactions at the injection site.

Uncommon side effects

Arrhythmias, bradycardia, chest pain, hiccups, hypotension, movement disorders including extrapyramidal reactions such as: dystonia, dyskinesia, oculogyric crisis (uncontrolled movement of the eye bulb), seizures. There have been cases of transient rise in liver enzymes.

Rare side effects

During intravenous use it may cause dizziness, transient visual disturbances.
Also, there have been rare reports with transient ECG changes including QT interval prolongation (Torsade de Pointes).

Very rare side effects

During intravenous use it may cause transient blindness.
If you notice side effects, including those not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ONDANSETRON

Keep out of the reach and sight of children.

Do not use Ondansetron after the expiry date stated on the package.

Do not store above 25°C.

Keep in the original packaging to protect it from the impact of external factors.

6. FURTHER INFORMATION

What Ondansetron solution for injection contains

The active substance is ondansetron hydrochloride dihydrate.

Each 4 ml ampoule contains 10 mg of ondansetron hydrochloride dihydrate (equivalent to 8 mg ondansetron).

The excipients are: citric acid monohydrate, sodium citrate dihydrate, sodium chloride, sodium hydroxide, water for injections.

Content of the pack

Box with 10 ampoules 4 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St.“Skënder Vila”,

Tirana, Albania.

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