Package leaflet: Information for the user

EMITINO TABLETS 4 mg
(Ondansetron Orally Disintegrating Tablets USP 4 mg)

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, ask your doctor, Healthcare provider, 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 gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor, health care proider or pharmacist.

In this leaflet:

a. What EMITINO TABLETS 4 mg is and what it is used for

Ondansetron is a potent, highly selective 5HTs receptor-antagonist. Its precise mode of action in the control of nausea and vomiting is not known. Chemotherapeutic agents and radiotherapy may cause release of 5HT in the small intestine initiating a vomiting reflex by activating vagal afferents via 5HTs receptors. Ondansetron blocks the initiation of this reflex. Activation of vagal afferents may also cause a release of 5HT in the area postrema, located on the floor of the fourth ventricle, and this may also promote emesis through a central mechanism. Thus, the effect of ondansetron in the management of the nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy is probably due to antagonism of 5HT3 receptors on neurons located both in the peripheral and central nervous system. The mechanisms of action in post-operative nausea and vomiting are not known but there may be common pathways with cytotoxic induced nausea and vomiting.

How EMITINO TABLETS 4 mg works

Adults

Ondansetron hydrochloride is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, and for the prevention and treatment of post-operative nausea and vomiting.

Pediatric Population

Ondansetron hydrochloride is indicated for the management of chemotherapy-induced nausea and vomiting (CINV) in children aged ≥6 months, and for the prevention and treatment of PONV in children aged ≥1 month.

b. Before you take EMITINO TABLETS 4 mg

Do not take EMITINO TABLETS 4 mg

- Do not take EMITINO TABLETS 4 mg if you are allergic to any of its contents.

Take special care with EMITINO TABLETS 4 mg

Warnings and precautions EMITINO TABLETS should be used with caution in patients with Hypersensitivity reactions to other selective 5HTs receptor antagonists. Respiratory events should be treated symptomatically and clinicians should pay particular attention to them as precursors of hypersensitivity reactions.

Children and adolescents

should be used with caution in children if prescribed by the doctor.

Other medicines

As per published data, there is no evidence that ondansetron either induces or inhibits the metabolism of other drugs commonly co-administered with it. Specific studies have shown that there are no pharmacokinetic interactions when ondansetron is administered with alcohol, temazepam, furosemide, alfentanil, tramadol, morphine, lidocaine, thiopental or propofol.

Ondansetron is metabolised by multiple hepatic cytochrome P-450 enzymes: CYP3A4, CYP2D6 and CYP1A2. Due to the multiplicity of metabolic enzymes capable of metabolising ondansetron, enzyme inhibition or reduced activity of one enzyme e.g. CYP2D6 genetic deficiency) is normally compensated by other enzymes and should result in little or no significant change in overall ondansetron clearance or dose requirement.

Phenytoin, Carbamazepine and Rifampicin: In patients treated with potent inducers of CYP3A4 (i.e. phenytoin, carbamazepine, and rifampicin), the oral clearance of ondansetron was increased and ondansetron blood concentrations were decreased.

Tramadol: Data from small studies indicate that ondansetron may reduce the analgesic effect of tramadol.

Use of ondansetron with QT prolonging drugs may result in additional QT prolongation. Concomitant use of ondansetron with cardiotoxic drugs (e.g. anthracyclines) may increase the risk of arrhythmias.

EMITINO TABLETS 4 mg with food and drink

No interactions found with food.

Avoid consumption of alcohol while taking **EMITINO TABLETS 4 mg** as it may cause increased dizziness.

Pregnancy and breast-feeding

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.

If you are taking Ondansetron, you should not breast-feed your baby.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Ondansetron is unlikely to affect your ability to drive or operate machinery.

C. How to take EMITINO TABLETS 4 mg

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

To protect you from nausea and vomiting during and after cancer treatment with cytostatic agents (chemotherapy) or radiation therapy:

Adults

On the day of chemotherapy or radiation therapy:

The usual dose is 8 mg Ondansetron, taken one to two hours before treatment, and a further 8 mg Ondansetron twelve hours later.

On the following days:

On the following days, you will receive Ondansetron in the form of orally disintegrated tablets (that dissolve in the mouth), film-coated tablets or as a solution. Always use this medicine exactly as described in this leaflet or as your doctor or nurse has told you.

The usual dose is 8 mg Ondansetron twice a day at 12 hour intervals for up to 5 days.

Use in children (aged 6 months and older) and adolescents

On the day of chemotherapy:

For children and adolescents, Ondansetron is available as a solution for injection, to be given before chemotherapy as a slow injection into a vein over at least 30 seconds.

On the following days, Ondansetron is given as orally disintegrated tablets, film-coated tablets or as a solution:

Your doctor will tell you the exact dose of Ondansetron for your child, depending on the child's size (body surface area) or weight. The maximum dose is up to 8 mg Ondansetron twice a day at 12-hour intervals for up to 5 days.

For the treatment of nausea and vomiting caused by radiation therapy, no data are available from controlled clinical studies on the use of ondansetron in children.

Elderly patients

No dose adjustment or change in dosing frequency is required.

Prevention of sickness (nausea and vomiting) after an operation:

Adults

Unless otherwise prescribed by the doctor, the usual dose is 16 mg Ondansetron, one hour before anaesthesia.

Use in children and adolescents

The doctor may decide to administer an injection rather than tablets.

Elderly patients

Experience with ondansetron in the prevention of nausea and vomiting after an operation in elderly patients is limited.

Patients with kidney problems

No dose adjustment is required.

Patients with liver problems

In patients with moderate to severely impaired liver function, the total daily dose should not be more than 8 mg.

Route of administration

The tablets should be taken by mouth. They will break up rapidly in the mouth and can then be swallowed. You should wash them down with a glass of water.

If you take more EMITINO TABLETS 4 mg than you should

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

If you forget to take EMITINO TABLETS 4 mg

Do not take a double dose to make up for a forgotten dose. Take your missed dose for nausea or vomiting as quickly as possible and then continue taking your medicine as normal.

If you are unsure what to do, ask your doctor or pharmacist.

If you stop taking EMITINO TABLETS 4 mg

Take Ondansetron for as long as your doctor recommends it. Do not stop unless advised by your doctor.

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

D. Possible side effects

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

Severe allergic reactions:

These are rare in patients taking Ondansetron. Signs of these may be:

• raised or itchy rash (hives).

• swelling, sometimes in the face or mouth (angioedema), which may cause breathing difficulties.

• collapse.

Myocardial ischaemia (frequency unknown):

Signs include:

• sudden chest pain or

• chest tightness

Contact your doctor or pharmacist immediately if you notice these symptoms and stop taking Ondansetron.

Other side effects

Very common: may affect more than 1 in 10 people

• headache.

Common: may affect up to 1 in 10 people

• sensation of warmth, hot flushes with skin redness.

• constipation.

Uncommon: may affect up to 1 in 100 people

• seizures.

• movement disorders or spasms (including extrapyramidal reactions such as muscle tone disorders, eye muscle disorders [oculogyric crisis] and motor disorders), but these were shown not to have any long-term clinical consequences.

• chest pain (with or without ST-segment depression on the ECG).

• irregular or slow heart beat (heart rhythm disorder, bradycardia).

• low blood pressure.

• hiccups.

• increase in substances (enzymes) produced by the liver (increase in liver function tests).

Rare: may affect up to 1 in 1,000 people

• severe allergic reactions.

• rhythm disorders (QT prolongation including torsade de pointes, which may cause a sudden loss of consciousness).

• temporary visual disturbances (e.g. blurred vision), mainly with IV administration.

• dizziness, mainly with rapid IV administration.

Very rare: may affect up to 1 in 10,000 people

• extensive rash with blistering and skin peeling over large areas of the skin surface (toxic epidermal necrolysis)

• temporary blindness, mainly with IV administration.

Side effects in children and adolescents

The side effect profile in children and adolescents was comparable to the side effect profile observed in adults.

E. How to store EMITINO TABLETS 4 mg

- 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 bottle and carton after "EXP". The expiry date refers to the last day of that month.
- Store in a dry place, below 30°C. Protected from light.
- Store in the original package in order to protect from moisture.
- 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.

F. Further Information

What **EMITINO TABLETS 4 mg** contains

- The active substance is Ondansetron.
- Contains Ondansetron USP 4mg.
- The other ingredients are: Magna Sweet (Mono Ammonium Glycyrrhizinate), Sucralose, Crospovidone, Mannitol DC (Perlitol SD 160), Avicel 200 (Microcrystalline Cellulose 200), Magnesium Stearate, Colour Sunset yellow Lake, Flavour Orange Powder (Trusil-Bush Boake) and Flavour Peppermint DC-117.

What **EMITINO TABLETS 4 mg** looks like and contents of the pack

- Light orange colour circular biconvex uncoated tablets having bisecting line on one side.
- Primary Container: 10 tablets packed in ALU/ALU Blister
- Secondary container: Such one blister in a printed outer carton along with Pack insert.

Marketing Authorization Holder

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