Package leaflet: Information for the user

EMITINO SYRUP
(Ondansetron Oral Solution USP

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 provider or pharmacist.

In this leaflet:

a. What EMITINO (Ondansetron Oral Solution USP) 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 (Ondansetron Oral Solution USP) works

1) Emitino is indicated for the management of nausea and vomiting induced by cytotoxic Chemo therapy and radiotherapy.

2) Emitino is also indicated fur 1he prevention and treatment of post-operative nausea and vomiting. Routine prophylaxis is not recommended for patients in whom here is little Expectation that nausea and vomiting will occur.

3) For the short-term treatment of nausea/vomiting associated with acute gastroenteritis:

b. Before you take EMITINO (Ondansetron Oral Solution USP)

Do not take EMITINO (Ondansetron Oral Solution USP)

- Do not take **EMITINO (Ondansetron Oral Solution USP)** if you are allergic to any of its contents.

Take special care with EMITINO (Ondansetron Oral Solution USP)

Warnings and precautions: Ondansetron is not a drug that stimulates gastric or intestinal peristalsis. It should not be used instead of nasogastric suction. The use of Ondansetron in patients following abdominal surgery or in patients with chemotherapy-induced nausea and vomiting may mask a progressive ileus and/or gastric distention.

Children and adolescents

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

Other medicines

Ondansetron does not itself appear to induce or inhibit the cytochrome P-450 drug-metabolizing enzyme system of the liver. Because Ondansetron is metabolized by hepatic cytochrome P-450 drug-metabolizing enzymes (CYP3A4, CYP2D6, CYP1A2), inducers or inhibitors of these enzymes may change the clearance and, hence, the half-life of Ondansetron. On the basis of limited available data, no dosage adjustment is recommended for patients on these drugs.

Renal impairment

No alteration of daily dosage or frequency of dosing or route of administration is required.

Hepatic impairment

Clearance of ondansetron is significantly reduced and serum half-life significantly prolonged in subjects with moderate or severe impairment of hepatic function. In such patients a total daily dose of 8 mg should not be exceeded

EMITINO (Ondansetron Oral Solution USP) with food and drink

No interactions found with food.

Avoid consumption of alcohol while taking **EMITINO (Ondansetron Oral Solution USP)** as it may cause increased dizziness.

Pregnancy and breast-feeding

Pregnancy

Category B. Emitino should be used during pregnancy only if clearly needed.

Lactation

It is not known whether Ondansetron is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ondansetron is administered to a nursing woman.

Driving and using machines

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

C. How to take EMITINO (Ondansetron Oral Solution USP)

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:

Chemotherapy and radiotherapy-

i) Children 4-11 year: 4 mg PO three times per day. The dosage schedule is the same as for adults. The first dose should be given 30minutes before the start of emetogenic chemotherapy, with two subsequent doses four hours and eight hours after the initial dose. Further doses may be given every 8 hours for 1-2 days after completion of chemotherapy. Dosage should be adjusted in hepatic impairment.

ii) Children < 4 years and BSA >1 m^2:4 mg PO three times per day.

Children < 4 years and BSA 0.6-1 m^2:3 mg PO three times per day. Children < 4 years and BSA 0.3.0.6 m^2: 2 mg PO1hree times per day. Children < 4 years and BSA < 0.3 m^2:1 mg PO1hree times per day.

iii) Adults including the elderly, adolescents, and children >= 12 years: 8 mg PO three times per day

Nausea/vomiting associated with acute gastroenteritis:

NOTE: In children, only the first dose of PO Ondansetron was statistically significant in reducing the overall frequency of vomiting (vs. placebo).Vomiting in gastroenteritis usually peaks on the first day; determine if additional doses of Ondansetron are required based on the patient's clinical status. Ondansetron may cause diarrhea and then therefore worsen dehydration in gastroenteritis.

Children 4-12 years: 4 mg PO; may administer every 8 hours if needed. Children 1-3 years:

3.2 mg PO; may administer every 8 hours if needed. Infants 6 months-1 year: 1.6 mg PO; may administer every 8 hours if needed. Infants< 1 month: Safety and efficacy have not been established.

If you take more EMITINO (Ondansetron Oral Solution USP) than you should

If you or your child take more EMITINO (Ondansetron Oral Solution USP) 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 (Ondansetron Oral Solution USP)

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 (Ondansetron Oral Solution USP 2)

Take EMITINO (Ondansetron Oral Solution USP) 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.
Ondansetron is known to increase large bowel transit time and may cause constipation in some patients. The following side effects can occur: headache, a sensation of flushing or warmth, and occasional transient asymptomatic increases in aminotransferase and possible extrapyramidal reactions.

There have been rare reports of immediate hypersensitivity reactions including anaphylaxis. Rare cases of Oculogyric crisis, transient visual disturbances (e.g. blurred vision) and dizziness have been reported during rapid intravenous administration of Ondansetron.

E. How to store EMITINO (Ondansetron Oral Solution USP)

- 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 below 30°C. Protect 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 (Ondansetron Oral Solution USP)** contains

- The active substance is Ondansetron Hydrochloride USP
- Contains Ondansetron Hydrochloride USP Equivalent to Ondansetron 8mg/5ml
- The other ingredients are: Sucrose BP, Propylene Glycol BP, Methyl Paraben BP, Propyl Paraben BP, Sodium Citrate BP, Citric acid (Monohydrate) BP, Colour Ponceau 4R, Flavour Fruit Mixed (Vital), Purified Water BP.

What **EMITINO (Ondansetron Oral Solution USP)** looks like and contents of the pack

- Pink colour clear liquid having sweet taste and pleasant flavor.
- Primary Container: 30 ml in Amber coloured Pet Bottle sealed with 25 mm EPE WAD Cap Secondary container: 10 ml transparent Measuring cups & Sticker Label as per text matter. Such one bottle in a printed outer carton along with Pack insert.

Marketing Authorization Holder

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