EMITOSS		
Module I	**REGIONAL ADMINISTRATIVE INFORMATION**	Cont ….
I.10	**The information printed on packaging: primary, secondary and package leaflet**	
	10.3. The Leaflet	

Parshwa Printer
Printing Packaging Trading

PRODUCT Name : **EMITOSS LEAFLET**

Please check below detailed & then give stamp & sign

CURRENT DATE & CORRECTION NUMBER	OLD PRODUCTION FILE DATE	CORRECTION IN WHICH COLOUR	Leaflet size:
07-12-2020 C5	NEW	FRONT/BACK	L.90 x H.163mm

FRONT

EMITOSS SYRUP

Ondansetron Oral Solution USP 2mg/5ml

Composition
Each 5 ml contains
Ondansetron hydrochloride USP equivalent to Ondansetron 2 mg
Flavoured Syrup Base.
Colour : Sunset yellow

Description
Ondansetron is a potent, highly selective $5HT_3$ 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 $5HT_3$ 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 nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy is probably due to antagonism of $5HT_3$ receptors or 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.

Indications
1) Emitoss is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.
2) Emitoss is also indicated for the prevention and treatment of post-operative nausea and vomiting. Routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and vomiting will occur.
3) For the short-term treatment of nausea/vomiting associated with acute gastroenteritis.

Dosage and Administration
Chemotherapy and radiotherapy-
1) Children 4-11 years: 4 mg three times per day. The dosage schedule is the same as for adults. The first dose should be given 30 minutes 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 three times per day.
Children < 4 years and BSA 0.6-1 m^2: 3 mg three times per day.
Children < 4 years and BSA 0.3-0.6 m^2: 2 mg three times per day.
Children < 4 years and BSA < 0.3 m^2: 1 mg three times per day.
iii) Adults including the elderly, adolescents, and children >=12 years: 8mg three times per day

Nausea/vomiting associated with acute gastroenteritis :
NOTE : In children, only the first dose of 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 therefore worsen dehydration in gastroenteritis.
Children 4-12 years: 4 mg may administer every 8 hours if needed.
Children 1-3 years: 3.2 mg ; may administer every 8 hours if needed.
Infants 6 months-1 year: 1.6 mg ; may administer every 8 hours if needed.
Infants < 1 month: Safety and efficacy have not been established.

Contraindications
Hypersensitivity to any components of the preparations.

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.

BACK

Drug Interactions
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 are 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.

Pregnancy
Ondansetron should not be used during the first trimester of pregnancy.

Lactation
Tests have shown that ondansetron passes into the milk of lactating animals.
It is therefore recommended that mothers receiving Ondansetron.
Oral Solution should not breastfeed their babies.

Paediatric use
Little information is available about use of Emitoss in children under 1 month of age for PONV.

Geriatric use
Dosage adjustment is not needed in patients over the age of 65 years.

Side effects
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.

Overdosage
There is no specific antidote for ondansetron overdose. Patients should be managed with appropriate supportive therapy. Individual doses as large as 150 mg and total daily dosages (three doses) as large as 252 mg have been administered intravenously without significant adverse events. These doses are more than 10 times the recommended daily dose.
In addition to the adverse events listed above, the following events have been described in the setting of ondansetron overdose: "Sudden blindness" (amaurosis) of 2 to 3 minutes' duration plus severe constipation occurred in one patient that was administered 72 mg of ondansetron intravenously as a single dose. Hypotension (and faintness) occurred in another patient that took 48 mg of oral ondansetron. Following infusion of 32 mg over only a 4-minute period, a vasovagal episode with transient second-degree heart block was observed. In all instances, the events resolved completely.

Storage conditions
Store below 30°C, protected from light.
keep out of reach of children.

Presentation
30 ml bottle with dropper & 10 ml plastic measuring cup.

Shake well before use.

Manufactured by:
Enicar Pharmaceuticals Pvt. Ltd.
J-214,215, 216, MIDC, Tarapur Industrial Area,
Boisar, Dist. Palghar - 401 506.

Manufactured for :
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