SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

EMITINO-4 INJECTION

Ondansetron Injection USP 2 mg/ml

2. Qualitative and Quantitative Composition

Each ml Contains:

Ondansetron Hydrochloride USP

Equivalent to Ondansetron …… 2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for Injection.

Clear colourless liquid filled in clear colour glass ampoule.

4. Clinical particulars:

4.1 Indications

Emitino is indicated for the prevention and treatment of post-operative nausea and vomiting (PONV), and for the prevention of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.

4.2 Dosage and Administration

1) Prevention of Postoperative Nausea and Vomiting:

Adults: The recommended I.V. dosage of Emitino for adults is 4 mg undiluted administered intravenously in not less than 30 seconds, preferably over 2 to 5 minutes, immediately before induction of anesthesia, or postoperatively if the patient experiences nausea and/or vomiting occurring shortly after surgery. Alternatively, 4 mg undiluted may be administered intramuscularly as a single injection for adults. While recommended as a fixed dose for patients weighing more than 40 kg, few patients above 80 kg have been studied. In patients who do not achieve adequate control of postoperative nausea and vomiting following a single, prophylactic, pre-induction, I.V. dose of ondansetron 4 mg, administration of a second I.V. dose of 4 mg ondansetron postoperatively does not provide additional control of nausea and vomiting.

The recommended dosage is ondansetron 16 mg given 1 hour before induction of anesthesia.

Children: The recommended I.V. dosage of Emitino for pediatric surgical patients (1 month to 12 years of age) is a single 0.1-mg/kg dose for patients weighing 40 kg or less, or a single 4-mg dose for patients weighing more than 40 kg.

The rate of administration should not be less than 30 seconds, preferably over 2 to 5 minutes immediately prior to or following anesthesia induction, or postoperatively if the patient experiences nausea and/or vomiting occurring shortly after surgery.

There is no experience with the use of Emitino Injection, in the prevention of postoperative nausea and vomiting in pediatric patients.

2) Prevention of Chemotherapy-Induced Nausea and Vomiting:

Adults: Prevention of Nausea and Vomiting Associated With Highly Emetogenic Cancer Chemotherapy:

The recommended I.V. dosage of Emitino for adults is a single 32-mg dose or three 0.15-mg/kg doses. A single 32-mg dose is infused over 15 minutes beginning 30 minutes before the start of emetogenic chemotherapy. With the three-dose (0.15-mg/kg) regimen, the first dose is infused over 15 minutes beginning 30 minutes prior to initiation of emetogenic chemotherapy. Subsequent doses (0.15 mg/kg) are administered 4 and 8 hours after the first dose of Emitino

The recommended adult oral dosage of Emitino is a single 24-mg tablet administered 30 minutes before the start of single-day highly emetogenic chemotherapy.

Children: Prevention of Nausea and Vomiting Associated With highly or Moderately Emetogenic Cancer Chemotherapy:

The dosage in pediatric cancer patients 6 months to 18 years of age should be three 0.15-mg/kg doses. The first dose is to be administered 30 minutes before the start of moderately to highly emetogenic chemotherapy; subsequent doses (0.15 mg/kg) are administered 4 and 8 hours after the first dose of Emitino. The drug should be infused intravenously over 15 minutes. Little information is available about dosage in pediatric cancer patients younger than 6 months of age.

3) Prevention of Nausea and Vomiting Associated With Radiotherapy, Either Total Body Irradiation, or Single High-Dose Fraction or Daily Fractions to the Abdomen:

The recommended oral dosage is ondansetron 8-mg given 3 times a day.

For total body irradiation, ondansetron 8-mg should be administered 1 to 2 hours before each fraction of radiotherapy administered each day.

For single high-dose fraction radiotherapy to the abdomen, ondansetron 8-mg should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for 1 to 2 days after completion of radiotherapy.

For daily fractionated radiotherapy to the abdomen, ondansetron 8-mg should be administered 1 to 2 hours before radiotherapy, with subsequent doses every 8 hours after the first dose for each day radiotherapy is given.

Children: There is no experience with the use of Emitino Tablets, in the prevention of radiation induced nausea and vomiting in pediatric patients.

4.3 Contraindications

Hypersensitivity to any components of the preparations.

4.4 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.

4.5 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 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.

4.6 Fertility, pregnancy and lactation

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.

Pediatric use

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

Geriatric use

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

4.7 Effects on ability to drive and use machines

Ondansetron has no influence on the ability to drive and use machines.

4.8 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.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Over dosage

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiemetics and antinauseants, Serotonin ($5HT_3$) antagonists

ATC Code: A04AA01

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.

5.3 Preclinical safety data

Preclinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients(s)

Sr. No.	Name of Product	Specification
1.	Citric Acid Monohydrate	USP
2.	Sodium Citrate	USP
3.	Water for Injection	USP

6.2 Incompatibilities

Ondansetron injection should not be administered in the same syringe or infusion as any other medication.

Ondansetron injection should only be mixed with those infusion solutions that are recommended.

6.3 Shelf Life

36 Months

6.4 Special precautions for storage

Store in a dry place, below 30^0 C. Protected from light.

Keep out of reach of children.

FOR IM/SLOW IV USE

6.5 Nature and contents of container

2 ml sterile solution for injection filled in 2 ml clear glass ampoule, duly labeled and such 10 ampoules packed in a plastic hip tray in a printed carton along with pack insert.

6.6 Special precautions for disposal and other handling For single use only. Discard any unused solution.

7. MARKETING AUTHORIZATION HOLDER

Cachet Pharmaceuticals Pvt. Ltd

415, Shah Nahar Industrial Estate,

Dr. E. Moses Road, Worli, Mumbai-400 018,

Maharashtra, India www.cachetindia.com

Manufacturer:

East African (India) Overseas

Plot: 1, Pharmacity,

Selaqui, Dehradun (INDIA)

8. MARKETING AUTHORIZATION NUMBER(S)

H2008/19972/851

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION DATE OF FIRST AUTHORIZATION : 07/04/2009

10. DATE OF REVISION OF THE TEXT

28/12/2024