SUMMARY OF PRODUCT CHARACTERISTICS

1. **Name of the medicinal product: EMITINO**

(Ondansetron Oral Solution USP 2mg/5ml)

2. Qualitative and quantitative composition:

Each 5 ml contains:

Ondansetron Hydrochloride USP	
Equivalent to Ondansetron	2.0 mg
Flavoured Syrupy Base	q.s.

3. Pharmaceutical form: Liquid Dosage Form (Solution)

4. Clinical particulars:

4.1 Therapeutic indications:

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

2) Emitino 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.

4.2 Posology and method of administration:

Chemotherapy and radiotherapy-

1) Children 4-11years:4 mg PO 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 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 PO three times per day.

Children < 4 years and BSA < 0.3 m^2: 1 mg PO three 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 therefore worsen dehydration in gastroenteritis.

Children4-12 yean: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 month-1 year: 1.6 mg PO; may administer every 8 hours If needed.

Infants < 1 month: Safety and efficacy have not been established.

tnon-US FDA-approved indication

4.3 Contraindications

Hypersensitivity to any ingredient of the formulation.

4.4 Special warnings and precautions for use

Respiratory events should be treated symptomatically and clinicians should pay particular attention to them as precursors of hypersensitivity reactions.

As ondansetron is known to increase large bowel transit time, patients with signs of subacute intestinal obstruction should be monitored following administration.

In patients with adenotonsillar surgery, prevention of nausea and vomiting with ondansetron may mask occult bleeding. Therefore, such patients should be followed carefully after ondansetron.

Paediatric patients receiving ondansetron with hepatotoxic chemotherapeutic agents should be monitored closely for impaired hepatic function.

4.5 Interaction with other medicinal products and other forms of interaction

Specific studies have shown that there are no interactions when ondansetron is administered with alcohol, temazepam, furosemide, alfentanil, tramadol, morphine, lidocaine, thiopental or propofol. Concomitant use of ondansetron with cardiotoxic drugs (e.g. anthracyclines (such as doxorubicin, daunorubicin) or trastuzumab), antibiotics (such as erythromycin), antifungals (such as ketoconazole), antiarrhythmics (such as amiodarone) and beta blockers (such as atenolol or timolol) may increase the

risk of arrhythmias.

Based on reports of profound hypotension and loss of consciousness when ondansetron was administered with apomorphine hydrochloride, concomitant use with apomorphine is contraindicated.

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. Ondansetron may reduce the analgesic effect of tramadol.

4.6 Pregnancy and lactation

Pregnancy

The safety of ondansetron for use in human pregnancy has not been established. Breast-feeding

Tests have shown that ondansetron passes into the milk of lactating animals. It is therefore recommended that mothers receiving Ondansetron should not breast-feed their babies.

4.7 Effects on ability to drive and use machines

Not known

4.8 Undesirable effects

Anaphylaxis, Headache, movement disorders, Dizziness during rapid IV administration, Cardiac disorders as Arrhythmias, chest pain, bradycardia., Vascular disorders as Sensation of warmth or flushing, Hypotension, Respiratory, thoracic and mediastinal disorders, Hiccups, Gastrointestinal disorders as Constipation and Hepatobiliary disorders as Asymptomatic increases in liver function tests.

4.9 Overdose

Symptoms and Signs

There is limited experience of ondansetron overdose. Manifestations that have been reported include visual disturbances, severe constipation, hypotension and a vasovagal episode with transient second-degree AV block.

Treatment

There is no specific antidote for Ondansetron, therefore in all cases of suspected overdose, symptomatic and supportive therapy should be given as appropriate. The use of ipecacuanha to treat overdose with Ondansetron is not recommended, as patients are unlikely to respond due to the anti-emetic action of Ondansetron itself.

5. Pharmacological properties

Mechanism of Action

Ondansetron is a potent, highly selective 5HT3 receptor-antagonist. Chemotherapeutic agents and radiotherapy may cause release of 5HT in the small intestine initiating a vomiting reflex by activating vagal afferents via 5HT3 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.

6. Pharmaceutical particulars

6.1 List of excipients: 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.

Incompatibilities

Not Applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C. Protect from Light.

Keep away from the reach of Children.

6.5 Nature and contents of container

30 ml amber coloured PET bottle with 10 ml measuring cup and dropper packed in a printed monocarton with pack insert.

6.6 Special precautions for disposal and other handling

Not Applicable

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING

SITE ADDRESSES

Cachet Pharmaceuticals Private Limited

Address: 415, Shah Nahar Ind. Estate,

Dr. E. Moses Road, Worli,

Mumbai-400 018

Maharashtra, India

Telephone: +91-22-24970011 / +91-22-40829999

8. MARKETING AUTHORISATION NUMBER

-Not Applicable

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

-Not applicable

10. DATE OF REVISION OF THE TEXT

-Not applicable

11. NAME AND ADDRESS OF MANUFACTURE

Cachet Pharmaceuticals Private Limited

Address: Village: Thana, Baddi, Himachal Pradesh-173 205, India