For the use of a Registered Medical Practitioner, Hospital or a Laboratory only.

Ondansetron Injection USP

EMISTOP™

COMPOSITION

Each ml contains:

Ondansetron Hydrochloride Dihydrate USP equivalent to Ondansetron	2 mg
Water for Injections BP	q.s.

DESCRIPTION

Ondansetron is a potent, highly selective 5-HT_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 5-HT in the small intestine initiating a vomiting reflex by activating vagal afferents via 5-HT_3 receptors. Ondansetron blocks the initiation of this reflex. Activation of vagal afferents may also cause a release of 5-HT 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 5-HT_3 receptors on neurons located both in the peripheral and central nervous system. The mechanism of action in post-operative nausea and vomiting are not known but there may be common pathways with cytotoxic-induced nausea and vomiting.

INDICATIONS

EMISTOP™ 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 (PONV).

ADULTS		CHILDREN	
DAY 1	DAY 2-5	DAY 1	DAY 2-5
HIGHLY EMETOGENIC CHEMOTHERAPY			
A single dose of 8 mg by slow intravenous injection immediately before chemotherapy OR A dose of 8 mg by slow intravenous injection immediately before chemotherapy followed by two further intravenous doses of 8 mg two to four hours apart, or by a constant infusion of 1mg/hour for upto 24 hours OR A single dose of 32 mg diluted in compatible infusion fluid and infused over a period of not less than 15 minutes immediately before chemotherapy	8 mg orally twice daily for up to 5 days 8 mg orally twice daily for up to 5 days 8 mg orally twice daily for up to 5 days	A single intravenous dose of 5 mg/m^2 immediately before chemotherapy followed by 4 mg orally twelve hours later	4 mg orally twice daily for up to 5 days

In highly emetogenic chemotherapy, efficacy of ondansetron over the first 24 hours may be enhanced by the addition of a single I. V. dose of 20 mg. Dexamethasone sodium phosphate prior to chemotherapy.

ADULTS		CHILDREN	
DAY 1	DAY 2-5	DAY 1	DAY 2-5
HIGHLY EMETOGENIC CHEMOTHERAPY			
A single dose of 8 mg administered as a slow intravenous injection immediately before chemotherapy / radiotherapy OR 8mg orally 1-2 hours before chemotherapy / radiotherapy	8 mg orally twice daily for upto 5 days OR 8 mg orally twice daily for upto 5 days	A single intravenous dose of 5 mg/m^2 immediately before chemotherapy followed by 4 mg orally twelve hours later.	4 mg orally twice daily for up to 5 days

RECOMMENDED INFUSION SOLUTIONS
In keeping with good pharmaceutical practice, intravenous solutions should be prepared at the time of infusion with the following recommended infusion solutions:
- Sodium Chloride Intravenous Infusion BP (0.9% w/v)
- Glucose Intravenous Infusion BP (5% w/v)
- Mannitol Intravenous Infusion BP (10% w/v)
- Ringers intravenous infusion
- Potassium Chloride 0.3% w/v and Glucose 5% w/v

FOR POST-OPERATIVE NAUSEA AND VOMITING (PONV)

Indications	Adults
For the prevention of post-operative nausea and vomiting	8 mg given orally one hour prior to anaesthesia followed by two further doses of 8 mg at eight hourly intervals OR A single dose of undiluted 4 mg given by slow intravenous injection at induction of anaesthesia
For the treatment of established post-operative nausea and vomiting.	A single dose of undiluted 4 mg given by slow intravenous injection

Children
There is no experience in the use of ondansetron in the prevention and treatment of post-operative nausea and vomiting in children.

Elderly
There is limited experience in the use of ondansetron in the prevention and treatment of post-operative nausea and vomiting in elderly.

CONTRAINDICATIONS
Hypersensitivity to any components of the preparation.

WARNINGS AND PRECAUTIONS
Pharmaceutical precautions: Dilutions of **EMISTOP™** injection in compatible intravenous infusion fluids are stable under normal room lighting conditions or daylight for at least 24 hours, thus no protection from light is necessary while infusion takes place. **EMISTOP™** injection should not be administered in the same syringe or infusion as any other medication. **EMISTOP™** injection ampoules should not be autoclaved.
Pregnancy : EMISTOP™ is not teratogenic in animals. There is no experience in humans. As with other medications, Emistop should not be used during pregnancy, especially during the first trimester, unless the expected benefit to the patient is thought to outweigh any possible risk to the foetus.
Lactation : Tests have shown that ondansetron is excreted in the breast milk of rats. It is therefore recommended that mothers receiving **EMISTOP™** should not breast-feed their babies.
Paediatric Use : Little information is available about dosage in children under 3 years of age.
Patients with renal impairment : No alteration of daily dosage, or frequency of dosing or route of administration are required.
Patients with 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.

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 in the head and epigastrium, occasional transient asymptomatic increases in the levels of aminotransferases and possible extra pyramidal reactions.
There have been rare reports of immediate hypersensitivity reactions including anaphylaxis. Rare cases of transient visual disturbances (e.g. blurred vision) have been reported during rapid intravenous administration of ondansetron.

OVERDOSAGE
Little at present is known about overdosage with ondansetron. However, two patients who received doses of 84 mg and 145 mg intravenously reported only mild side effects and required no active therapy. In case of suspected overdosage, symptomatic and supportive therapy should be given as appropriate.

STORAGE
Store between 2°C to 30°C. Protect from light.

PRESENTATION
EMISTOP™ is available in 2ml and 4ml glass ampoule.

Manufactured by :
Claris Lifesciences Limited
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1400002717