

Pukenil®

Ondansetron

COMPOSITION:

Pukenil® Tablet : Each Film coated tablet contains Ondansetron 8 mg as Ondansetron Hydrochloride USP.
Pukenil® Syrup : Each 5 ml syrup contains Ondansetron 4 mg as Ondansetron Hydrochloride USP.

PHARMACOLOGY:

Ondansetron is a highly specific and selective serotonin 5-HT₃ receptor antagonist with low affinity for dopamine receptor. The 5-HT₃ receptors are present both peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema in the medulla. Serotonin is released by the enterochromaffin cells of the small intestine in response to chemotherapeutic agents and many stimulate vagal afferents (via 5-HT₃ receptors) to initiate the vomiting reflex. It is thought that Ondansetron's antiemetic action is mediated mostly via antagonism of vagal afferents with a minor contribution from antagonism of central receptors.

INDICATION:

Ondansetron is a serotonin subtype 3 (5-HT₃) receptor antagonist indicated: Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy. Prevention and treatment of post operative nausea and vomiting. Prevention of radiotherapy induced nausea and vomiting.

DOSE & ADMINISTRATION:

Prevention of chemotherapy induced nausea & vomiting (C1NV): Adult: Tablet and syrup-The recommended adult oral dosage of Ondansetron is 24 mg given as three 8 mg tablets in highly emetogenic chemotherapy. In case of moderately emetogenic chemotherapy the oral dose is one 8 mg Ondansetron tablet or 10 ml of Ondansetron syrup given twice daily. Pediatric patients: Tablet and Syrup - For pediatric patients 4 through 11 years of age the dosage is one 4 mg Ondansetron tablet or 5 ml of Ondansetron syrup should be administered 3 times a day for 1 to 2 days after completion of chemotherapy.

Radiotherapy induced nausea and vomiting: Adult: Tablet and syrup- The recommended oral dosage is one 8 mg Ondansetron tablet or 10 ml of Ondansetron syrup given 3 times daily.

Post operative nausea & vomiting (PONV): Adult: Tablet and syrup- The recommended dosage is 16 mg given as two 8 mg Ondansetron tablets or 20 ml of Ondansetron syrup 1 hour before induction of anesthesia.

Dosage adjustment for patients with impaired hepatic function: Tablet and Syrup- The total daily dose of 8 mg should not be exceeded.

Geriatric Use: Dosage adjustment is not needed in patients over the age of 65.

CONTRA-INDICATION:

Contraindicated in patients known to have hypersensitivity to the drug or any of its components. Concomitant use of apomorphine.

WARNING AND PRECAUTION:

Hypersensitivity reactions, including anaphylaxis and bronchospasm, have been reported in patients who have exhibited hypersensitivity to other selective 5-HT₃ receptor antagonists.

Hepatic Impairment: A total daily dose of 8 mg should not be exceeded (patients with severe hepatic impairment).

Renal Impairment: No dosage adjustment is recommended.

SIDE EFFECTS:

Generally Ondansetron is well tolerated. However few side effects including headache, diarrhoea, fatigue, dizziness and constipation may be seen after ondansetron is administered.

USE IN PREGNANCY & LACTATION:

US FDA Pregnancy Category: B.

Reproduction studies have been performed in pregnant rats and rabbits at daily oral doses up to 15 and 30 mg/kg per day respectively and have revealed no evidence of impaired fertility or harm to the fetus due to Ondansetron. There are, however, no adequate and well controlled studies on a pregnant women. Ondansetron is excreted in the breast milk of rats. So caution should be exercised when Ondansetron is administered to a nursing mother.

USE IN CHILDREN & ADOLESCENTS:

The use of oral Ondansetron of children and adolescents is supported due to extensive evidence from its use in oncology and in a range of others setting including gastroenteritis. Ondansetron is considered safer than other antiemetics in children and adolescents, where the risk of dystonic reaction is higher.

DRUG INTERACTION:

The potential for clinically significant drug interactions with Ondansetron appears to be low.

OVERDOSE:

There is no specific antidote for Ondansetron overdose. If overdose is occurred, symptomatic and supportive therapy should be give as appropriate.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Pukenil® Tablet : Each box contains 3 x 10's tablets in Alu-Alu blister pack.

Pukenil® Syrup : Each bottle contains 50 ml syrup with a 10 ml measuring cup.



Manufactured by

Team Pharmaceuticals Ltd.

B 75-79, BSCIC, Rajshahi, Bangladesh

IST-0034