Pukenil®

Ondansetron USP

COMPOSITION:

Pukenil ® 50 ml Oral Solution: Each 5 ml oral solution contains Ondansetron 4 mg as Ondansetron Hydrochloride USP.

PHARMACOLOGY:

Ondansetron is a selective 5-HT3 receptor antagonist. While its mechanism of action has not been fully characterized, ondansetron is not a dopamine-receptor antagonist. Serotonin receptors of the 5-HT3 type are present both peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema. It is not certain whether ondansetron's antiemetic action is mediated centrally, peripherally or in both sites. However, cytotoxic chemotherapy appears to be associated with release of serotonin from the enterochromaffin cells of the small intestine.

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: The recommended adult dose: 10 ml of Ondansetron oral solution given twice daily.

Pediatric patients: For pediatric patients 4 through 11 years of age the dosage is 5ml of Ondansetron solution should be administered 3 times a day for 1 to 2 days after completion of chemotherapy.

Radiotherapy induced nausea and vomiting: Adult: The recommended oral dosage is 10 ml of Ondansetron Oral Solution given 3 times daily.

Post operative nausea & vomiting (PONV): Adult: 20 ml of Ondansetron Oral Solution 1 hour before induction of anesthesia.

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 with or without known hypersensitivity to other selective 5-HT3 receptor antagonists. QT prolongation occurs in a dose-dependent manner.

SIDE EFFECT:

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 AND LACTATION:

Pregnancy: Pregnancy Category B

Nursing Mothers: Ondansetron is excreted in the breast milk of rats. 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.

USE IN CHILDREN & ADOLESCENTS:

The use of oral ondansetron for children and adolescents is supported due to extensive evidence from its use in oncology and in a range of other settings 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.

ADVERSE REACTION:

The most common adverse reactions in chemotherapy-induced nausea and vomiting (incidence 7%) are diarrhea, headache and fever. The most common adverse reactions in post operative nausea and vomiting in adults is headache (incidence 10%) and in pediatric patients aged 1 to 24 months is diarrhea (incidence 2%).

OVERDOSE:

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

STORAGE:

Store in a dry & cool place below 30^{0} C temperature and keep away from light & moisture. Keep the medicine out of reach of children.

PACKING:

Pukenil ® 50 ml Oral Solution: Each 5 ml oral solution contains Ondansetron 4 mg as Ondansetron Hydrochloride USP.

Manufactured by

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