Onsat®

Ondansetron

Oral soluble film

Description

Onsat® (ondansetron) oral soluble film is a orally dissolving film designed to be applied on top of the tongue where it will dissolve within 20 seconds and then is swallowed with saliva.

Onsat® does not require water to aid dissolution or swallowing. The active ingredient in Onsat® is ondansetron base, the racemic form of ondansetron, and a selective blocking agent of the serotonin 5-HT3 receptor type. The empirical formula is $C_{18}H_{19}N_3O$ representing a molecular weight of 293.3.

Indications and Usage

Onsat® is a 5-HT3 receptor antagonist indicated for:

- Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy.
- Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
- Prevention of nausea and vomiting associated with radiotherapy in patients receiving total body irradiation, single high-dose fraction to abdomen, or daily fractions to the abdomen.
- Prevention of postoperative nausea and/or vomiting.

Dosage and Administration

Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy: The adult oral dosage is 24 mg given successively as three 8 mg films 30 minutes before the start of chemotherapy.

Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy:

- Adults and pediatric patients 12 years of age and older: One 8 mg film 30 minutes before chemotherapy followed by an 8 mg dose 8 hours later. Administer one 8 mg film twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.
- Pediatric patients 4 through 11 years of age: One 4 mg film three times a day. Administer the first dose 30 minutes before chemotherapy, with subsequent doses 4 and 8 hours later. Administer one 4 mg film three times a day (every 8 hours) for 1 to 2 days after completion of chemotherapy.
- Prevention of nausea and vomiting associated with radiotherapy: The adult dosage is one 8 mg film three times a day.
- Postoperative nausea and vomiting: The adult dose is 16 mg given successively as two 8 mg films 1 hour before anesthesia.

See dosage adjustment for patients with impaired hepatic function.

Instructions for Use

(peel of the pouch)

Step 1. Tear the pouch carefully along with the edge tear mark.

Step 2. Put the Onsat film on top of your tongue. It will dissolve within 20 seconds.

Step 3. Do not chew or swallow the film whole.

Step 4. Swallow after the Onsat® oral soluble film dissolves. You may swallow the dissolved film with or without liquid.

Step 5. Wash your hands after taking Onsat® oral soluble film.

Contraindications

- Concomitant use of apomorphine.
- Hypersensitivity to ondansetron.

Warnings and Precautions

- Hypersensitivity reactions, including anaphylaxis and bronchospasm, have been reported in patients who have exhibited hypersensitivity to other selective 5-HT3 receptor antagonists.
- The use of ondansetron in patients following abdominal surgery or in patients with chemotherapy-induced nausea and vomiting

Adverse Reactions

- The most common adverse drug events (≥ 5%) in chemotherapy-induced nausea and vomiting and radiotherapy-induced nausea and vomiting trials were: headache, malaise/fatigue, constipation, and diarrhea.
- The most common adverse event (≥5%) in postoperative nausea and vomiting trials was headache.

Drug Interactions

Apomorphine- profound hypotension and loss of consciousness.

Use in Specific Populations

Pediatrics: The safety and effectiveness in pediatric patients have only been established for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in patients four years of age and older.

Impaired Hepatic Function: In severe hepatic impairment (Child-Pugh score of 10 or greater) 2, a total daily dose of 8 mg should not be exceeded.

Storage

Store at controlled room temperature 20° to 25°C (68° to 77°F). Store pouches in cartons. Keep product in pouch until ready to use.

Commercial Pack

Onsat® 4 oral soluble film: Box containing 10 Individual pouches of oral soluble film. Each film contains 4 mg Ondansetron USP.

Onsat® 8 oral soluble film: Box containing 10 Individual pouches of oral soluble film. Each film contains 8 mg Ondansetron USP.

Onsat IM/IV Injection: Box containing 1 x 5 ampoules of 4 ml in blister pack. Each 4 ml ampoule contains Ondansetron Hydrochloride USP equivalent to Ondansetron 8 mg.

Onsat® 8 Tablet: Each box contains 30 tablets in 3x10's blister strips. Each film coated tablet contains Ondansetron Hydrochloride USP equivalent to Ondansetron 8 mg.

Onsat® Syrup: Bottle containing 50 ml syrup. Each 5 ml contains Ondansetron Hydrochloride USP equivalent to Ondansetron 4 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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