Anset®

Ondansetron

Description
Ondansetron (**Anset®**) is a selective 5-hydroxytryptamine-3 (5-HT_3) receptor antagonist with anti-emetic activity.

Mode of action
Ondansetron (**Anset®**) is a potent, highly selective 5-HT_3 receptor antagonist. The effect of ondansetron in the management of the nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy is probably due to antagonism of 5-HT_3 receptors on neurons located both in the peripheral and central nervous system. The mechanisms of action in postoperative nausea and vomiting are not known but there may be common pathways with cytotoxic induced nausea and vomiting.

Pharmacokinetics
Ondansetron (**Anset®**) is well absorbed from the gastrointestinal tract and undergoes some first-pass metabolism. Mean bioavailability in healthy subjects is approximately 56% and bioavailability is also slightly enhanced by the presence of food and at higher doses but unaffected by antacids.

Composition
Anset® 4 mg Tablet: Each film coated tablet contains Ondansetron Hydrochloride Dihydrate USP 4.989 mg equivalent to Ondansetron 4 mg.
Anset® 8 mg Tablet: Each film coated tablet contains Ondansetron Hydrochloride Dihydrate USP 9.978 mg equivalent to Ondansetron 8 mg.
Anset® 4 ml IV/IM injection: Each injection contains Ondansetron Hydrochloride USP 9.978 mg equivalent to Ondansetron 8 mg.
Anset® 50 ml oral solution: Each 5 ml solution contains Ondansetron Hydrochloride Dihydrate USP 4.989 mg equivalent to Ondansetron 4 mg.
Anset® 16 mg suppository: Each suppository contains Ondansetron Hydrochloride Dihydrate USP 19.955 mg equivalent to Ondansetron 16 mg.

Indications
Ondansetron (**Anset®**) is indicated for the prevention and treatment of post-operative nausea and vomiting and for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.

Dosage and Administration
For oral preparation:
Postoperative nausea and vomiting:
The recommended dosage is 16 mg as two 8 mg **Anset®** tablets 1 hour before induction of anesthesia.
Chemotherapy induced nausea and vomiting:

a. For highly emetogenic cancer chemotherapy: The recommended adult oral dosage is three 8 mg **Anset®** tablets administered 30 minutes before the start of single-day highly emetogenic chemotherapy including cispiatin≥50 mg/m^2

b. *For moderately emetogenic cancer chemotherapy*: The recommended adult oral dosage is one 8 mg **Anset®** tablet given twice a day. The first dose should be administered 30 minutes before the start of emetogenic chemotherapy, with a subsequent dose 8 hours after the first dose and **Anset®** tablet should be administered twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.

Pediatric use: For pediatric patients 4 to 11 years age, the dosage is one 4 mg **Anset®** tablet given three times a day (every 8 hours).
Radiotherapy induced nausea and vomiting:
The recommended oral dosage is one 8 mg **Anset®** tablet given three times a day.
For total body irradiation, 8 mg **Anset®** Tablet should be administered 1 to 2 hours before each fraction of radiotherapy administered each day.
For single high-dose fraction radiotherapy to the abdomen, one 8 mg **Anset®** Tablet should be administered 1 to 2 hours before radiotherapy with subsequent doses every 8 hours after the first for 1 to 2 days after completion of radiotherapy.
Dosage adjustment for patients with impaired renal function: The dosage recommendation is the same as for the general population.
Dosage adjustment for patients with impaired hepatic function: In patients with severe hepatic impairment, a total daily dose of 8 mg should not be exceeded.

For Injection:
Prevention of Chemotherapy-Induced Nausea and Vomiting: The recommended IV/IM dosage of **Anset®** is a single 32 mg dose or three 0.15 mg/kg doses. A single 32 mg dose is infused over 15 minutes beginning 30 minutes before the start of emetogenic chemotherapy. Subsequent doses (0.15 mg/kg) are administered 4 and 8 hours after the first dose of **Anset®**.
Pediatric Use: The dosage in pediatric patients 4 to 18 years of age should be three 0.15 mg/kg doses. *Prevention of Postoperative Nausea and Vomiting*: The recommended IV/IM dosage of **Anset®** for adults is 4 mg undiluted administered intravenously is not less than 30 seconds, preferably over 2 to 5 minutes, immediately before induction of anesthesia, or postoperatively if the patient experiences nausea and/or vomiting occurring shortly after surgery. In patients who do not achieve adequate control of postoperative nausea and vomiting following a single, prophylactic, preinduction, IV/IM dose of ondansetron 4 mg, administration of a second IV/IM dose of 4 mg ondansetron postoperatively does not provide additional control of nausea and vomiting.

For suppository:
On the day of chemotherapy or radiotherapy:
- The usual dose is one suppository (16 mg) to be inserted 1 to 2 hours before treatment.

On the following days:
- The usual dose is one suppository (16 mg) each day
- This may be repeated for up to 5 days.

Contraindication
Ondansetron are contraindicated for patients known to have hypersensitivily to the drug.

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
Pregnancy: There are however, no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.
Nursing mother: 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 women.

Precautions
Ondansetron is not a drug that stimulates gastric or intestinal peristalsis. It should not be used instead of nasogastric suction. The use of Ondansetron in patients following abdominal surgery or in patients with chemotherapy induced nausea and vomiting may mask a progressive ileus and/or gastric distension.

Drug Interactions
Ondansetron does not appear to induce or inhibit the cytochrome P-450 drug-metabolizing enzyme system of the liver. Because Ondansetron is metabolized by hepatic cytochrome P-450 drug-metabolizing enzymes. Induces or inhibitors of these enzyme may change the clearance and hence, the half-life of Ondansetron. On the basis of available data, no dosage adjustment of Ondansetron is recommended for patients on these drugs.

Overdosage
There is no specific antidote for ondansetron overdose. In addition to the adverse events, hypotension (and faintness) occurred in a patient that took 48 mg of **Anset**®. Tablet in all instances, the events resolved completely.

Storage
Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging
Anset® 4 mg Tablet: Each carton contains 14X3 tablets in Alu-Alu blister pack.
Anset® 8 mg Tablet: Each carton contains 14X3 tablets in Alu-Alu blister pack.
Anset® 4 ml IV/IM injection: Each carton contains 5X2 ampoules in blister pack.
Anset® 50 ml oral solution: Each amber plastic bottle contains 50 ml oral solution.
Anset® 16 mg Suppository: Each carton contains 5X2 suppositories in strip pack.

Opsonin Pharma
Ideas for healthcare

Manufactured by
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