Tablets / oral solution

ONSETRON

(Ondansetron Hydrochloride)

اونسیٹرون

گولیاں/اورل سولیوشن

(اونڈنسیٹرون ھائیڈروکلورائیڈ)

COMPOSITION:

Each Film Coated Tablet Contains:
Ondansetron Hydrochloride Dihydrate eq. to Ondansetron 8mg
Each 5ml contains:
Ondansetron Hydrochloride Dihydrate eq. to Ondansetron ..... 4 mg
(Product contains gluten/lactose)

INDICATIONS:

For the prevention of nausea and vomiting associated with emetogenic chemotherapy including high dose cisplatin and radiotherapy. Ondansetron is also indicated for the prevention and treatment of post-operative nausea and vomiting.

CLINICAL PHARMACOLOGY:

Ondansetron is a selective antagonist of the serotonin receptor subtype, 5-HT_3. Its precise mode of action in the control of chemotherapy induced nausea and vomiting is not known. Cytotoxic chemotherapy and radiotherapy are associated with the release of serotonin (5-HT_3) from enterochromaffin cells of the small intestine, presumably initiating a vomiting reflex through stimulation of 5-HT_3 receptors located on vagal afferents. Ondansetron may block the initiation of this reflex, activation of vagal afferents may also cause a central release of serotonin from the chemoreceptor trigger zone of the area postrema, located on the floor of the fourth ventricle, thus, the antiemetic effect of Ondansetron is probably due to the selective antagonsim of 5-HT_3 receptors on neurons located in either the peripheral or central nervous system, or both. The mechanisms of Ondansetron's antiemetic action in post-operative nausea and vomiting are not known.

CONTRAINDICATIONS:

Ondansetron is contraindicated in patients with history of hypersensitivity of the drug or any component of its formulation.

DOSAGE AND ADMINISTRATION:

CHEMOTHERAPY INDUCED NAUSEA AND VOMITING:

The recommended dose is:

To prevent nausea and vomiting from chemotherapy

Adults: On the day of chemotherapy or radiotherapy

- the usual dose is 10ml (8mg) taken one to two hours before treatment and another 10ml (8mg) twelve hours after.

On the following days

- the usual dose in 10ml (8mg) twice a day, this may be given for up to 5 days.

Children and adolescents (6 months to 17 years):

The doctor will decide the dose depending on the child's size (body surface area) or weight.

- the usual dose for a child is up to 5mg (4mg) twice a day
- this can be given for up to 5 days.

To prevent nausea and vomiting after an operation

Adults:

The usual dose is 20ml (16mg) before your operation.

Children aged over 1 month and adolescents:

It is recommended that Ondansetron is given as an injection.

Patients with moderate or severe liver problems:

The total daily dose should not be more than 10ml (8mg).
Ondansetron should start to work within one or two hours of taking a dose.

If you are sick (vomiting) within one hour of taking a dose:

- take the same dose again
- otherwise, do not take more Ondansetron than recommended.

If you continue to feel sick, tell your doctor..

PRECAUTIONS:

Ondansetron is not effective in preventing motion induced nausea and vomiting. There is no experience in patients who are clinically jaundiced. In patients with moderate to severe hepatic function, reductions in dosage are therefore recommended and a total daily dose of 8mg should not be exceeded. This may be given as a single dose.

Pregnancy: The safety of Ondansetron during pregnancy has not been established, it should not be used if outweigh the possible risk to the fetus.

Lactation: Ondansetron is excreted in the milk of lactating rats. It is not known if it is excreted in human milk, however, nursing is not recommended during treatment with Ondansetron.

Children: Insufficient information is available to provide dosage recommendations for 3 years of age or under.

ADVERSE EFFECTS:

Ondansetron has been administered to over 2500 patients worldwide in controlled clinical trials and has been well tolerated. The most frequent adverse events reported in controlled clinical trials were headache (11%) and constipation (4%). Other adverse events include sensations of flushing or warmth (1%(.

Metabolic: There were transient increases of AST and ALT of over twice the upper limit of normal in approximately 5% of patients. This increase did not appear to be related to dose or duration of therapy. There have been reports of liver failure and death in patients with cancer receiving concurrent medications including potentially hepatotoxic, cytotoxic chemotherapy and antibiotics. The etiology of the liver failure is unclear. There have been rare reports of hypokalemia.

CNS: There have been rare reports of seizures.

Hypersensitivity: Rare cases of immediate hypersensitivity reaction sometime severe, including anaphylactic, Bronchospasm, Urticaria and Angioedema have been reported.

Cardiovascular: There have been rare reports of tachycardia angina (chest pain). Bradycardia, hypotension, syncope and electrocardiogrphic alteration.

Dermatological: Rash has occurred in approximately 1% patients receiving Ondansetron.

Special Senses: Rare cases of transient visual disturbance (e.g.,, blurred vision) have been reported.

Other: There have been reports of abdominal pain, weakness and exrostonia.

OVER DOSAGE:

Symptoms and Treatment: At present there is little informaiotn concerning overdosage with Ondansetron and total daily doses as large as 252mg have been administered with only mild side effects. There is no specific antidote for Ondansetron, therefore, in cases of suspected over dosage, symptomatic and supportive therapy should be given as appropriate.

INSTRUCTIONS:

Store in a dry place below 30°C and protect from sunlight. Keep out of reach of the children To be sold on prescription of a registered medical practitioner only.

PRESENTATION:

1. **Onsetron Tablets 8mg:** Blister pack of 10's Tablets.
2. **Onsetron oral solution 4mg/5ml:** As pack of 50ml syrup filled in 60ml amber colored PET bottle.

خوراک:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

خشک جگہ پر ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

سورج کی روشنی سے بچائیں۔

تمام دوائیں بچوں کی دسترس سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

Manufactured by:
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