Odafen™

Fexofenadine Hydrochloride USP

Composition:
Odafen™ 120: Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.
Odafen™ 180: Each film coated tablet contains Fexofenadine Hydrochloride USP 180 mg.
Odafen™ Suspension: Each 5 ml suspension contains Fexofenadine Hydrochloride USP 30 mg.

Pharmacology:
Fexofenadine Hydrochloride is an antihistamine with selective peripheral H_1-receptor antagonist activity. Fexofenadine is rapidly absorbed after oral doses with peak plasma concentrations being reached in 2-3 hours. It is about 60% to 70% bound to plasma proteins. About 5% of the total doses is metabolized, mostly by the intestinal mucosa, with only 0.5% to 1.5% of the dose undergoing hepatic biotransformation by the cytochrome P450 system. Elimination half-life of 14 hours has been reported although this may be prolonged in patients with renal impairment. Excretion is mainly in the faeces with only 10% being present in the urine. Fexofenadine does not appear to cross the Blood-Brain Barrier.

Indication:
Seasonal Allergic Rhinitis:
Odafen™ tablet are indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older. Odafen™ oral suspension is indicated for the relief of symptoms associated with seasonal allergic rhinitis in children 2 to 11 years of age. Symptoms to treat effectively: sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes.

Chronic Idiopathic Urticaria:
Odafen™ tablets are indicated for treatment of uncomplicated skin manifestations of Chronic Idiopathic Urticaria in adults and children 6 years of age and older. Odafen™ suspension is indicated for treatment of uncomplicated skin manifestations of Chronic Idiopathic Urticaria in children 6 months to 11 years of age. Fexofenadine Hydrochloride significantly reduces pruritus and the number of wheals.

Dosage and Administration:

Age group	Odafen™ Tablet	Odafen™ Suspension
Adults and Children 12 years and older	120 mg once daily or 180 mg once daily with water	---
Children 6 to 11 years	---	30 mg (5 ml) twice daily
Children 2 to 5 years	---	30 mg (5 ml) twice daily
Children 6 months to less than 2 years	---	15 mg (2.5 ml) twice daily

For patients with decreased renal function, care should be taken in dose selection **Or as directed by the physician**.

Contraindication:
Patients with known hypersensitivity to Fexofenadine and any of the ingredients of Odafen™.

Warnings & Precautions:
This drug is known to be substantially excreted by the kidney and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function. Initial doses of Fexofenadine Hydrochloride in patients with renal impairment should be reduced to 60 mg once daily.

Side Effects:
The most common side effects in subjects age 12 years and older were headache, back pain, dizziness, stomach discomfort. In subjects aged 6 to 11 years, cough, upper respiratory tract infection, pyrexia and otitis media were more frequently reported. In subjects aged 6 months to 5 years, vomiting, diarrhea, fatigue and rhinorrhea were more frequently reported.

Use in Pregnancy & Lactation:
There are no adequate and well-controlled studies in pregnant women. Fexofenadine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known if Fexofenadine is excreted in human milk. Caution should be exercised when Fexofenadine is administered to lactating mother. Because many drugs are excreted in human milk, so caution should be exercised when Fexofenadine is given to a nursing mother.

Use in Children & Adolescents:
The safety and efficacy of Fexofenadine for the treatment of allergic rhinitis in children younger than 2 years of age and Chronic Idiopathic Urticaria in infants less than 6 months of age has not been established.

Drug Interaction:
Plasma concentrations of Fexofenadine have been increased when given with Erythromycin or Ketoconazole. Antacid containing Aluminium and Magnesium Hydroxide reduces the absorption of Fexofenadine. Fruit juices including grapefruit may reduce the bioavailability of Fexofenadine and use together should be avoided.

Overdose:
Reports of Fexofenadine Hydrochloride overdose have been infrequent and contain limited information. However, dizziness, drowsiness and dry mouth have been reported. In the event of overdose, consider standard measures to remove any unabsorbed drug.

Storage:
Store below 30^0C., away from light and in a dry place. Keep all medicines out of the reach of children.

Packing:
Odafen™ 120: Each box contains 5 X 10 tablets in blister pack and an insert.
Odafen™ 180: Each box contains 3 X 10 tablets in blister pack and an insert.
Odafen™ Suspension: Each box contains a bottle of 50 ml suspension and an insert.

Manufactured by:
Navana Pharmaceuticals Ltd.
Rupshi, Rupganj, Narayanganj, Bangladesh
NAVANA PHARMA
JAHURUL ISLAM COMPANY
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