

Nerupa[®]

Rupatadine 10 mg

COMPOSITION:

Nerupa[®] 10 Tablet: Each film coated tablet contains Rupatadine Fumarate BP equivalent to Rupatadine 10 mg.

Nerupa[®] Syrup: Each 5 ml syrup contains Rupatadine Fumarate BP equivalent to Rupatadine 5 mg.

PHARMACOLOGY:

Rupatadine is a long-acting, non-sedative antagonist of histamine H1-receptors. It also antagonizes the platelet-activating factor (PAF). Both histamine and PAF cause bronchoconstriction which leads to an increase in the vascular permeability and act as a mediator in the inflammatory process. Rupatadine possesses other anti-allergic properties such as the inhibition of the degranulation of mast cells induced by immunological and non-immunological stimuli and inhibition of the release of cytokines, particularly of the tumor necrosis factor alpha (TNF α) in human mastocytes and monocytes.

INDICATION:

Rupatadine is indicated for the symptomatic treatment of seasonal & perennial allergic rhinitis and urticaria.

DOSE & ADMINISTRATION:

Adults and adolescents (over 12 years): The recommended dose is 10 mg once a day. Rupatadine may be taken with or without food.

Children aged 2 to 11 years:

Children weighing 25 kg or above: 1 teaspoonful (5 ml) of the oral solution once daily with or without food.

Children weighing equal or more than 10 kg to less than 25 kg: 1/2 teaspoonful (2.5 ml) oral solution once daily with or without food.

CONTRA-INDICATION:

Hypersensitivity to Rupatadine or to any of the excipients.

WARNING AND PRECAUTION:

Use of Rupatadine is not recommended in patients with renal or hepatic insufficiency, as no relevant clinical data is available. Administration of a dose of 10 mg daily of Rupatadine has not shown significant effects on the function of the central nervous system as seen in specific studies done for psychomotor function. Nevertheless, the patient should take precaution in driving or managing machines.

SIDE EFFECTS:

The most common undesirable effects are sleepiness, general weakness & fatigue.

USE IN PREGNANCY & LACTATION:

There is no clinical data available on the exposure of Rupatadine during pregnancy. Pregnant women should therefore not use Rupatadine, unless the potential benefit outweighs the potential risk for the fetus. No information is available, whether Rupatadine is excreted in the mother's milk. Therefore, it should not be used during lactation, unless the potential benefits for the mother justify the potential risk to the infant.

USE IN CHILDREN & ADOLESCENTS:

Rupatadine is not for use in children under 2 years of age or weighing less than 10 kg.

DRUG INTERACTION:

CYP3A4 inhibitors like Erythromycin & Ketoconazole inhibits both the pre-systemic and systemic metabolism of Rupatadine. Due to this potential interaction, it is not recommended to use Rupatadine in combination with Ketoconazole or any other inhibitors of CYP3A4. Co administration of Rupatadine and CNS depressants or alcohol may increase CNS depressant effect.

OVERDOSE:

No case of overdose has been reported in adults and children. In a clinical safety study in adults rupertadine at daily dose of 100 mg during 6 days was well tolerated. The most common adverse reaction was somnolence. If accidental ingestion of very high doses occurs symptomatic treatment together with the required supportive measures should be given.

STORAGE:

Store below 30^o C, protected from light & moisture. Keep in dry and cool place. Keep out of reach of children.

PACKING:

Nerupa[®] 10 Tablet: Each box contains 3X10's tablets in blister pack.

Nerupa[®] Syrup: Each bottle contains 60 ml syrup and 10 ml measuring cup.



Manufactured by

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