

Rupaday®

Rupatadine Fumarate BP Tablet & Oral Solution

COMPOSITION

Rupaday® Tablet:

Each tablet contains Rupatadine Fumarate BP equivalent to Rupatadine 10 mg.

Rupaday® Oral Solution:

Each 5 mL oral solution contains Rupatadine Fumarate BP equivalent to Rupatadine 5 mg.

DESCRIPTION

Rupaday® is a preparation of Rupatadine Fumarate. Rupatadine is a non-sedating antiallergic compound which displays strong antagonist activity towards both histamine H1 receptors and Platelet-Activating Factor (PAF) receptors. PAF and histamine are known to complement and promote secretion of each other. PAF induces vasodilatation and an increase in vascular permeability, which may be responsible for the appearance of rhinorrhoea and nasal congestion. PAF may have a major role in the late phase allergic reaction. Rupatadine's PAF antagonistic activity represents the likely mechanism behind the inhibition of eosinophil migration which has been suggested to be beneficial in the treatment of chronic urticaria.

INDICATIONS

- Seasonal allergic rhinitis
- Perennial allergic rhinitis and
- Chronic idiopathic urticaria

DOSAGE AND ADMINISTRATION

Adults and adolescents (over 12 years of age):

Rupaday Tablet:

The recommended dose is 10 mg/day (one tablet/day), with or without food.

Rupaday Oral Solution:

Children aged 2 to 11 year:

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.

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

CONTRAINDICATIONS

Hypersensitivity to Rupatadine Fumarate.

SIDE EFFECTS

- Somnolence
- Headache
- Fatigue

PRECAUTION AND WARNING

Cardiac safety of Rupatadine was assessed in a QT/QTc study. Rupatadine at even 10 times the therapeutic dose did not produce any effect on the ECG or have any pro-arrhythmic side effects. Rupatadine tablets should be used with caution in elderly patients (65 years and older). Although no overall differences in effectiveness or safety were observed in clinical trials, higher sensitivity of some older individuals cannot be excluded.

USE IN PREGNANCY AND LACTATION

Pregnancy category B2. Clinical data for Rupatadine or other compounds of the class are inadequate to establish safety in pregnancy. Until such data are available, Rupatadine should be used in pregnancy only if the expected benefits clearly outweigh potential risks to mother and foetus. Rupatadine is excreted in animal milk. It is unknown whether Rupatadine is excreted into breast milk. Due to the lack of human data, Rupatadine should be used in breast feeding mothers only if the expected benefits clearly outweigh potential risks to mother and child.

PHARMACEUTICAL PRECAUTION

Rupaday® Tablet: Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

Rupaday® Oral Solution: Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Rupaday® Tablet:

Box containing 3 strips of 10 tablets each. Each tablet contains Rupatadine Fumarate BP equivalent to Rupatadine 10 mg.

Rupaday® Oral Solution:

Bottle containing 60 mL oral solution. Each 5 mL oral solution contains Rupatadine Fumarate BP equivalent to Rupatadine 5 mg.

SK•F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

© REGD. TRADEMARK

PM03486 V03