

Rupatadine

RECOMMENDED CHANGES TO THE PRODUCT INFORMATION

The following changes to the product information of medicinal products containing the active substance <name of active substance> are recommended:

Summary of product characteristics

- Section 4.8

The following adverse reaction(s) should be added under the SOC Immune system disorders with a frequency rare:

hypersensitivity reactions (including anaphylactic reactions, angioedema and urticaria)

Package leaflet

Section 4

The following adverse reaction should be added: hypersensitivity reactions (including anaphylactic reactions, angioedema and urticaria) with a frequency rare.
