Ilaxten 10 mg orodispersible tablets and 2.5mg/ml oral solution (bilastine)
Prescribing Information

Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.

Presentation: Orodispersible tablets (ODT): round, slightly biconvex white tablets containing 10 mg bilastine. Oral Solution (OS): clear, colourless, slightly viscous aqueous solution.

Use: Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria in children aged 6 to 11 years with a body weight of at least 20 kg.

Dosage and administration: Oral administration. Children aged 6 to 11 years with a body weight of at least 20 kg. ODT: Take 1 tablet once daily. OS: Take 4 ml of oral solution once daily. ODT and OS: Take one hour before or two hours after food or fruit juice. Children under 6 years: no information. In adults and adolescents (over 12 years of age) the administration of Ilaxten 20 mg tablets is appropriate.

Contra-indications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions: Avoid co-administration with P-glycoprotein inhibitors in patients with moderate or severe renal impairment. Do not use in children under 6 years of age.

Interactions: No interaction data available for children. Consider interactions as for adults: food, grapefruit juice, ketoconazole, erythromycin, diltiazem; medicinal products that are substrates or inhibitors of P-gp, such as cyclosporine.

Pregnancy and Lactation: Avoid use during pregnancy.

Side-effects: Common: rhinitis, headache, allergic conjunctivitis, abdominal pain/upper abdominal pain. Uncommon: dizziness, loss of consciousness, eye irritation, diarrhoea, nausea, lip swelling, eczema, urticaria, fatigue. Frequency not known: palpitations, tachycardia, hypersensitivity reactions, and vomiting.

Package quantities and prices: ODT: 30 orodispersible tablets: £5.00. OS: One bottle containing 120 ml oral solution: £5.00.

Legal Category: POM.

Marketing Authorisation Numbers: PL 16239/0044-0045.

Marketing Authorisation Holder: Menarini International Operations Luxembourg S.A, 1 Avenue de la Gare, L-1611 Luxembourg.

Marketed by: A. Menarini Farmaceutica Internazionale SRL.

Further information is available on request to A. Menarini Farmaceutica Internazionale SRL, Menarini House, Mercury Park, Wycombe Lane, Wooburn Green, Buckinghamshire, HP10 0HH UK or may be found in the SmPC.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to A. Menarini Farmaceutica Internazionale SRL. Phone no. 0800 085 8678 or email: menarini@medinformation.co.uk