ABBREVIATED PRESCRIBING INFORMATION

GRAZAX® Abbreviated Prescribing Information.
Please refer to the Summary of Product Characteristics before prescribing. **Pharmaceutical Form and Composition:** GRAZAX® are oral lyophilisates (tablets) for specific immunotherapy that contain SQ standardised allergen extract of Timothy grass pollen *(Phleum pratense)* at a strength of 75,000 SQ-T per tablet. **Therapeutic Indications:** Disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older) with clinically significant symptoms and a positive skin prick test and/or specific IgE test to grass pollen. **Posology and Method of Administration:** The daily dose is one tablet to be placed under the tongue. Avoid swallowing for about 1 minute. It is recommended that the first tablet is taken under medical supervision (20–30 minutes). Clinical effect in the first grass pollen season is expected when treatment is initiated at least 4 months prior to the expected start of the grass pollen season. If treatment is initiated 2-3 months before the season some efficacy may also be obtained. It is recommended to continue treatment with GRAZAX® for a period of 3 years. Treatment should be initiated by physicians with experience in treatment of allergic diseases and the capability to treat allergic reactions. **Clinical Efficacy:** In adults continuous daily treatment with GRAZAX® resulted in a statistically significant improvement in symptoms and medication scores for 3 treatment years and 2 follow up years compared to placebo. No data in children beyond one grass pollen season is available. **Contraindications:** Hypersensitivity to excipients, malignancy or systemic diseases affecting the immune system, inflammatory conditions in the oral cavity with severe symptoms. Uncontrolled or severe asthma (Adults: FEV1 < 70% of predicted value, children: FEV1 < 80% of predicted value, after adequate pharmacologic treatment). **Special Warnings and Precautions for Use:** Oral surgery, shedding of a deciduous tooth in children, asthma deterioration, children with concomitant asthma and experiencing an acute upper respiratory tract infection. Rare cases of severe systemic allergic reactions have been reported therefore medical supervision at start of treatment is an important precaution. In patients who have previously had a systemic reaction to grass pollen subcutaneous immunotherapy, the risk of experiencing a severe reaction with GRAZAX® may be increased. Initiation of GRAZAX® should be carefully considered and measures to treat reactions should be available. Severe allergic reactions may be treated with adrenaline. The effects of adrenaline may be potentiated in patients treated with tricyclic antidepressants and monoamineoxidase inhibitors (MAOIs) with possible fatal consequences; this should be taken into consideration prior to initiating specific immunotherapy. **Interaction with other Medicinal Products and other forms of Interaction:** Concomitant therapy with symptomatic anti-allergic agents (e.g. antihistamines, corticosteroids and mast cell stabilisers) may increase the tolerance level of the patient to immunotherapy. No data exists on possible risks of simultaneous immunotherapy with other allergens. **Pregnancy and Lactation:** No clinical experience. Animal studies do not indicate increased risk. Treatment should not be initiated during pregnancy. **Undesirable Effects:** In studies, 56% of patients reported undesirable effects during the first 3 months of treatment. This number decreased markedly during further treatment. Very commonly reported adverse reactions in adult and paediatric patients treated with GRAZAX® were local allergic reactions in the mouth which mostly were mild to moderate. In the majority of patients the reactions start early in therapy, last from minutes to hours and tend to subside spontaneously within 1 to 7 days. If the patient experiences significant adverse events, anti-allergic medication should be considered. In case of severe systemic reactions, angioedema, difficulty in swallowing, difficulty in breathing, changes in voice, feeling of fullness in the throat or asthma deterioration, a physician should be contacted immediately. In children and adolescents the adverse event profile is similar to that observed in adults, with a more frequent report of non-serious systemic allergic reaction, conjunctival irritation, pharyngeal erythema, lip blister, salivary gland enlargement, erythema, ear pain and chest pain than in the adult population. **Overdose:** In adults doses up to 1,000,000 SQ-T have been tolerated. No data is available in children regarding exposure to doses above the recommended daily dose of 75,000 SQ-T. **Excipients:** Gelatin (fish source), mannitol, sodium hydroxide. **Shelf Life:** 5 years. **Content of Container:** Aluminium blister cards with 30 tablets. **Legal Category:** POM. **Marketing Authorisation Holder:** ALK-Abelló A/S, Bøge Alle 6–8, DK-2970 Hørsholm, Denmark. UK Office: ALK-Abelló Ltd, 1 Manor Park, Manor Farm Road, Reading, Berkshire, RG2 0NA. Telephone: 01189 037940. **Marketing Authorisation Number:** PA1255/004/001. **Updated:** Aug 2019. **Item Code:** 1375GIR.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie
Adverse events should also be reported to ALK-Abelló Ltd