EBGLYSS®▼ (lebrikizumab) PRESCRIBING INFORMATION
Please consult the Summary of Product Characteristics (SmPC) before prescribing

EBGLYSS® 250 mg solution for injection in pre-filled syringe. EBGLYSS® 250 mg solution for injection in pre-filled pen.
Active Ingredient: Each single-use pre-filled syringe or pen contains 250 mg of lebrikizumab in 2 mL solution (125 mg/mL). Lebrikizumab is produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology. **Indication:** EBGLYSS® is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older with a body weight of at least 40 kg who are candidates for systemic therapy. **Dosage and Administration:** The recommended dose of lebrikizumab is 500 mg (two 250 mg injections) at both week 0 and week 2, followed by 250 mg administered subcutaneously every other week up to week 16. Consideration should be given to discontinuing treatment in patients who have shown no clinical response after 16 weeks of treatment. Some patients with initial partial response may further improve with continued treatment every other week up to week 24. Once clinical response is achieved, the recommended maintenance dose of lebrikizumab is 250 mg every fourth week. Lebrikizumab can be used with or without topical corticosteroids (TCS). Topical calcineurin inhibitors (TCI) may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas. *Missed dose:* If a dose is missed, the dose should be administered as soon as possible. Thereafter, dosing should be resumed at the regular scheduled time. *Elderly (≥ 65 years):* No dose adjustment is recommended for elderly patients. *Renal and hepatic impairment:* No dose adjustment is recommended for patients with renal or hepatic impairment. *Body weight:* No dose adjustment for body weight is recommended. *Paediatric population:* The safety and efficacy of lebrikizumab in children aged 6 months to <12 years or adolescents 12 to 17 years of age and weighing less than 40 kg have not yet been established. No data are available. **Contraindications, Precautions and Warnings:** *Contraindications:* Hypersensitivity to the active substance or to any of the excipients listed. *Precautions:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. If a systemic hypersensitivity reaction (immediate or delayed) occurs, administration of lebrikizumab should be discontinued and appropriate therapy initiated. Patients treated with lebrikizumab who develop conjunctivitis that does not resolve following standard treatment should undergo ophthalmological examination. Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if lebrikizumab will influence the immune response against helminth infections by inhibiting IL-13 signalling. Patients with pre-existing helminth infections should be treated before initiating treatment with lebrikizumab. If patients become infected while receiving lebrikizumab and do not respond to antihelminth treatment, treatment with lebrikizumab should be discontinued until infection resolves. Prior to initiating therapy with lebrikizumab, it is recommended that patients are brought up to date with all age-appropriate immunisations according to current immunisation guidelines. Live and live attenuated vaccines should not be given concurrently with lebrikizumab as clinical safety and efficacy has not been established. Immune responses to non-live vaccines were assessed in a combined tetanus, diphtheria and acellular pertussis vaccine (TdaP) and a meningococcal polysaccharide vaccine. *Fertility, pregnancy and lactation:* There are limited amount of data from the use of lebrikizumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of lebrikizumab during pregnancy. It is unknown whether lebrikizumab is excreted in human milk or absorbed systemically after ingestion. Maternal IgG is known to be present in human milk. A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue from lebrikizumab therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. Animal studies showed no impairment of fertility. **Undesirable effects:** The most common adverse reactions are conjunctivitis (6.9%), injection site reactions (2.6%), conjunctivitis allergic (1.8%) and dry eye (1.4%). *Common (≥1/100 to <1/10):* Conjunctivitis, conjunctivitis allergic, dry eye, injection site reaction. *Uncommon (≥1/1 000 to <1/100):* Herpes zoster, eosinophilia, keratitis, blepharitis. Please consult Summary of Product Characteristics for further information. **Marketing Authorisation Number(s):** EU/1/23/1765/001; EU/1/23/1765/002; EU/1/23/1765/003; EU/1/23/1765/004; EU/1/23/1765/005; EU/1/23/1765/006; EU/1/23/1765/007; EU/1/23/1765/008; EU/1/23/1765/009; EU/1/23/1765/010; EU/1/23/1765/011; EU/1/23/1765/012. **Further information available from:** Almirall, S.A, Ronda General Mitre, 151 08022 Barcelona, Spain.