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IAD

Ebglyss®
lebrikizumab

Almirall IAD Symposium

Expert Insights into Lebrikizumab

This is a promotional meeting organised and funded by Almirall Ltd. This symposium is intended for UK & Ireland healthcare professionals only. Prescribing information and adverse event reporting information can be found on the next page.

Thursday 8th May, Europa Hotel, Belfast
18:30-20:30

Faculty:

Professor Alan Irvine
Consultant Dermatologist, Children's Health Ireland & St James's Hospital, Dublin

Professor Michael Ardern-Jones
Consultant Dermatologist, Southampton Hospital, Southampton

Join experts in the management of moderate to severe atopic dermatitis to discuss where lebrikizumab, a new treatment option, fits in the armamentarium

6.30pm Registration, Light snacks & Tea /Coffee

7.15pm **Expert Insights into Lebrikizumab**

- Targeting what matters
- Interpreting key clinical data
- Theory into practice : Case Studies

8.15pm Panel Discussion / Q&A

8.30pm Close & Fork Supper

Click for Prescribing Information UK

UK-Adverse events should be reported.
Reporting forms and information can be found at MHRA https://yellowcard.mhra.gov.uk
Adverse events should also be reported to Almirall Ltd.
Tel. 0800 0087 399

IE-Adverse events should be reported.
Reporting forms and information can be found at HPRA Pharmacovigilance, Website: www.hpra.ie.
Adverse events should be also reported to Almirall Ltd.
Email Almirall@EU.ProPharmaGroup.com

Ebglyss® ▼ (lebrikizumab) PRESCRIBING INFORMATION

Please consult the Summary of Product Characteristics (SmPC) before prescribing

Ebglyss 250 mg solution for injection in pre-filled syringe or pen
Active Ingredient: Each single-use pre-filled syringe or pen contains 250 mg 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 of age and older who are at least 40 kg who are candidates for systemic therapy.

Dosage and Administration: The recommended dose of Ebglyss for adult patients and adolescent patients ≥ 12 years of age and weighing at least 40 kg is an initial dose of 500 mg (two 250 mg injections) at week 0 and week 2, followed by 250 mg every other week administered as subcutaneous injection up to week 16. Clinical response is usually observed within 16 weeks of treatment. An initial partial response may further improve with continued treatment up to week 24. Once clinical response is achieved, the recommended maintenance dose of Ebglyss is 250 mg every four (4) weeks. Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment. Do not inject into tender, damaged, bruised, or scarred skin. Rotate injections sites with each injection. Ebglyss can be used with or without topical corticosteroids (TCS). Topical calcineurin inhibitors (TCI) to be reserved for problem areas only. *Elderly:* No dose adjustment is recommended. *Renal or hepatic impairment:* No dose adjustment recommended. *Children* The safety and efficacy of lebrikizumab in children aged 6 months to <12 years or adolescents 12 to 17 years weighing less than 40 kg have not yet been established. No data are available. *Consult SmPC for full method of administration.*

Contraindications, Precautions and Warnings:
Contraindications: Hypersensitivity to the active substance(s) or to any of the excipients listed in SmPC section 6.1.

Precautions: 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 (see SmPC section 4.8). Patients with pre-existing helminth infections should be treated before initiating lebrikizumab. Treatment with lebrikizumab should be discontinued if helminth infection occurs until infection resolves. Prior to initiating therapy with lebrikizumab, consider completion of all age-appropriate immunizations according to current immunization guidelines. Do not use live and live attenuated vaccines in patients treated with lebrikizumab.

Interactions: No interaction studies have been performed. Patients receiving lebrikizumab may receive concurrent inactivated or non-live vaccinations (see SmPC section 4.4). Given that lebrikizumab is a monoclonal antibody, no pharmacokinetic interactions are expected. *Consult SmPC and package leaflet for more information.*

Fertility, pregnancy, and lactation:
Fertility: Animal studies showed no impairment of fertility.
Pregnancy: Animal studies did not indicate indirect or direct harmful effects. As a precautionary measure, it is preferable to avoid the use of Ebglyss in pregnancy.
Breast-feeding: A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Ebglyss therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy.
Consult SmPC for more information.

Adverse Reactions: *Very common:* none. *Common:* conjunctivitis, conjunctivitis allergic, dry eye, injection site reaction. *Uncommon:* herpes zoster, eosinophilia, keratitis, blepharitis. *Rare:* none. *Very rare:* none. *Not known (cannot be estimated from available data):* none. *Consult SmPC for further information.*

Legal Category: POM

Price & Pack:
2 x 250 mg solution for injection in pre-filled syringe: Price to wholesaler
2 x 250 mg solution for injection in pre-filled pen: Price to wholesaler
Marketing Authorisation Number(s):
Pre-filled syringe: EU/1/23/1765/002
Pre-filled pen: EU/1/23/1765/008

For more information contact: Almirall Ltd, Harman House, 1 George Street, Uxbridge, UB8 1QQ, United Kingdom.

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