23 January 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Ebglyss▼ 250 mg solution for injection in pre-filled pen and prefilled syringe (lebrikizumab):

Interim Supply of Great Britain Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Almirall Limited ensuring supply of Ebglyss 250 mg solution for injection in pre-filled pen and prefilled syringe (lebrikizumab) to Northern Ireland.

To ensure continuity of supply, Almirall Limited has obtained approval from the MHRA to supply Northern Ireland product Ebglyss 250 mg solution for injection in prefilled pen, Batch # 2A, 671 units and Ebglyss 250 mg solution for injection in pre-filled syringe Batch # 2A, 400 units with packs intended for the Great Britain market. These are expected to be on the Northern Ireland market from 05 February 2024 for 6 months.

Ebglyss is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years of age and older with a body weight of at least 40 kg who are candidates for systemic therapy.

Please note the following:

- These products are considered licensed in Northern Ireland.
- These products from Great Britain have the same formulation as the Northern Ireland product.
- These products from Great Britain are manufactured according to the same manufacturing process and quality controls as the Northern Ireland product.
- There are minor differences between the Great Britain and the Northern Ireland product information. Key difference is the legal status (POM) is to be placed under the heading United Kingdom/Northern Ireland in the Blue Box Area on the outer cartons.
- Please ensure the UK Ebglyss Summary of Product Characteristics (SPC) and Patient Information Leaflets (PILs) are followed.
- Please refer to the UK approved SPC and PIL supplied with the Great Britain packs. These are also available on eMC Northern Ireland – *see QR codes below*.
- For additional copies of the leaflet, please refer to eMC Northern Ireland or contact the company contact point by telephoning the freephone number: 0800 731 6789.

Almirall Limited
Harman House
1 George Street
Uxbridge, UK
Tel: +44 207 160 2522
almirall.com

- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer packaging of Ebglyss 250 mg solution for injection in pre-filled pen and syringe.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

QR Code for eMC Northern Ireland – Ebglyss 250 mg solution for injection in pre-filled pen.

QR Code for eMC Northern Ireland – Ebglyss 250 mg solution for injection in pre-filled syringe

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Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼
- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

- Ebglyss▼ is subject to additional monitoring. This will allow quick identification of new safety information.
- Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card scheme.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies, and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

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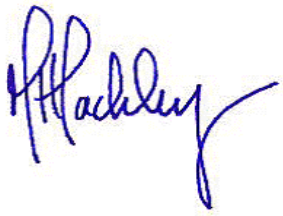
Company contact point
If you have any questions about this letter or require more information about Ebglyss 250 mg solution for injection in pre-filled pen and syringe, please contact Almirall Limited Medical Information: telephone 0800 0087 399. This is a 24/7 telephone number provided by Almirall Limited.

Yours faithfully,



Marie-Helene Tackley, BSc (Hons)
Pharmaceutical Affairs Manager
Almirall Limited

T. +44 0207 160 2500
M. +44 7827 445 157
marie.helene.tackley@almirall.com

Harman House
1 George Sreet, Uxbridge, Middlesex, UB8 1QQ – GB