ATOPIC ECZEMA AND EBGLYSS® (LEBRIKIZUMAB)

IMPORTANT INFORMATION about atopic eczema and its treatment with **EBGLYSS**

You have received this brochure because your doctor has prescribed **EBGLYSS** for your atopic eczema.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See **www.yellowcard.mhra. gov.uk** for how to report side effects. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

GLOSSARY

ANTIBODY – a protein in the blood which helps protect you when an unwanted substance (called an antigen) is in your body.

ALLERGEN – any substance that causes (triggers) an allergic reaction in a person who is sensitive to it.

INTERLEUKIN – any of a group of naturally occurring proteins that mediate communication between cells. (source: www.britannica.com)

You have been prescribed the EBGLYSS prefilled pen

You have been prescribed the EBGLYSS prefilled syringe

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ATOPIC ECZEMA AND WHAT CAUSES IT

What is atopic eczema?

Atopic eczema, also known as atopic dermatitis, is one of the most common long-term inflammatory skin conditions.

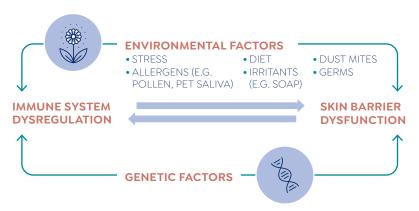
Itch and dry, scaly and/or cracked skin can be constant symptoms of atopic eczema. During eczema flare-ups, skin may become red (or darker, in skin of colour), sore, blistered and very itchy. This can affect the whole body.



- 1. Harrop J, et al. Clin Exp Allergy. 2007;37(4):526-535.
- 2. Diepgen TL, et al. Br J Dermatol. 2016;174(2):319-329.
- 3. Saeki H, et al. J Dermatol. 2006;33(11):817-819.
- 4. Sacotte R, Silverberg JI. Clin Dermatol. 2018;36(5):595-605.

What causes atopic eczema?

While the exact cause of atopic eczema is not fully known, several key factors may contribute to it.

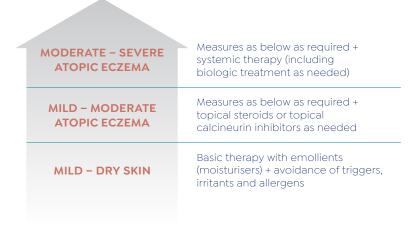


- The immune system may behave differently in people with atopic eczema. A protein called IL-13 can be overproduced and lead to inflammation.
- The skin barrier (the uppermost layer of skin) can stop working effectively, which may allow the entry of allergens and irritants, and loss of water through the skin.
- **Genetic factors** play a role. If you have parents with eczema, or another atopic condition, you have a greater chance of developing eczema yourself.
- Environmental factors may be involved. These include pollution, allergens, and certain chemicals.

TREATMENT OF ATOPIC ECZEMA

How is atopic eczema treated?

Treatment of atopic eczema depends on the severity of the condition. For everyone with atopic eczema,
emollients (medical moisturisers) are the foundation of
treatment, in addition to avoidance of triggers, irritants and
allergens. Topical steroid ointments or creams are then
used for short term treatment of flare-ups.





Your dermatologist or another healthcare professional will help you decide which treatment is best for your symptoms.

BIOLOGIC TREATMENTS FOR ATOPIC ECZEMA

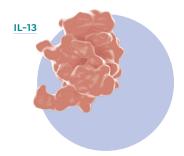
What are biologic treatments?

Biologic treatments are proteins that target and bind to specific substances that cause a reaction from your body's immune system.

Today, specifically-designed biologic treatments are used to treat many diseases, including atopic eczema.

To develop a biologic treatment, researchers first have to identify what to target.

In atopic eczema, one such substance is IL-13, a protein which plays a key role in the condition.



HOW EBGLYSS WORKS

EBGLYSS is a biologic treatment that is specially designed to target the protein IL-13.

EBGLYSS binds to IL-13 and helps stop it causing skin problems and itch.¹

^{1.} Miron Y, Miller PE, Hughes C, et al. J Allergy Clin Immunol. 2022; S0091-6749(22)00233-0

DOSING AND FORMAT

EBGLYSS is available in two formats, a prefilled pen and prefilled syringe. Talk with your dermatologist or nurse about which might be best for you.



The single-dose prefilled pen offers:

- Can be used by patients at home
- Hidden and automated needle
- 15 second injection time
- Confirmation that you received the full dose
- You'll hear 2 clicks, one when you start the injection,
 and one at the end to tell you that the injection is complete



The single-dose prefilled syringe offers:

- A way to control speed of injection
- Can be used by patients at home

Storing EBGLYSS



After removing **EBGLYSS** from the refrigerator, the syringe or prefilled pen should be allowed to **reach room temperature** inside the carton by waiting for **45 min** before injecting. The device must not be heated in the microwave, placed in hot water or put in direct sunlight.



EBGLYSS should be stored in the **refrigerator**, but it can be stored in the original package at **room temperature for up to 7 days or discarded**. Once stored outside the refrigerator, do not put it back in.

Disposing of EBGLYSS



Put your used pen or syringe in a **strong**, **tight-closing**, **puncture- and leak-proof container immediately after use**.

GETTING STARTED WITH EBGLYSS



- Tell your doctor or pharmacist if you are using or planning to use any other medicines.
- Always follow the recommended dosing for EBGLYSS as advised by your doctor or pharmacist.

Adult patients and adolescent patients (12 to 17 years of age and weighing at least 40 kg)

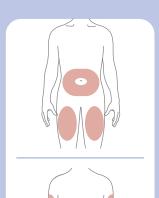


After taking **EBGLYSS** every 2 weeks for 16 weeks, most people will have the option to switch to dosing every 4 weeks.*

^{*}The recommended dose of **EBGLYSS** is 500 mg (two 250 mg injections) at both week 0 and week 2, followed by 250 mg every 2 weeks up to week 16. Some people with initial partial response may further improve with continued treatment every 2 weeks up to week 24. Once clinical response is achieved, the recommended maintenance dose is 250 mg every fourth week.

HOW TO USE THE **EBGLYSS** PEN

Place the **EBGLYSS** prefilled pen, kept inside the carton, on a flat surface and let it warm to room temperature naturally for at least 45 minutes before use. Then remove it from the carton. The device must not be heated in the microwave, placed in hot water or put in direct sunlight.



Choose your injection site

You or another person may inject into these areas:

- **Stomach area (abdomen)** At least 5 cm away from your belly button (navel).
- Front of thigh At least 5 cm above your knee and 5 cm below your groin.
- Back of upper arm Another person should inject into the back of your upper arm.

Choose a different injection site each time you inject **EBGLYSS**.



2 Uncap the pen

- Make sure the pen is locked.
- When you are ready to inject, twist off the grey base cap and throw the cap away in your household waste.
- Do not put the grey base cap back on this could damage the needle.
- Do not touch the needle inside the clear base.



3 Place and unlock

- Place and hold the clear base flat and firmly against the skin.
- Keep the clear base on the skin, then turn the lock ring to the unlock position.



4 Press and hold for 15 seconds

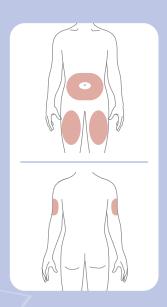
- Press and hold the purple injection button and listen for two loud clicks:
 - First click = injection started
 - Second click = injection completed
- The injection may take up to 15 seconds.
 You will know the injection is complete when the grey plunger is visible.



5 Dispose of the pen safely

Put your used pen in a strong, tight-closing, puncture- and leak-proof container immediately after use. Do not re-use prefilled pens or syringes.

HOW TO USE THE EBGLYSS SYRINGE



Place the **EBGLYSS** prefilled syringe, kept inside the carton, on a flat surface and let it warm to room temperature naturally for at least 45 minutes before use. Then remove it from the carton. The device must not be heated in the microwave, placed in hot water or put in direct sunlight.

Choose your injection site

You or another person may inject into these areas:

- Stomach area (abdomen) At least 5 cm away from your belly button (navel).
- Front of thigh At least 5 cm above your knee and 5 cm below your groin.
- Back of upper arm Another person should inject into the back of your upper arm.

Choose a different injection site each time you inject EBGLYSS.

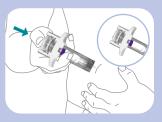


2 How to inject EBGLYSS

- Hold the EBGLYSS prefilled syringe in the middle of the syringe body with the needle pointing away from you, and pull off the needle cap.
- **Pinch the injection site.** Gently pinch a fold of skin at the injection site (thigh or stomach, except for 5 cm around your belly button, or outer area of the upper arm if injected by someone else).



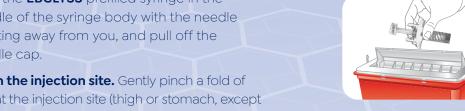
Insert the needle. Insert the needle completely into the fold of skin at about a 45° angle.



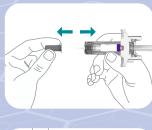
Push in the plunger rod. Gently relax the pinch while keeping the needle in place. Slowly and steadily push the plunger rod down all the way until it stops and the syringe is empty. Note: It is normal to feel some resistance.



Release and remove. Lift your thumb to release the plunger rod until the needle is covered by the needle safety device, and then remove the syringe from the injection site. Lightly press a cotton wool ball or gauze on the injection site if you see any blood. Do not put the needle cap back on. Do not rub your skin after injection.



Dispose of the syringe safely. Put your used syringe and needle cap in a strong, tight-closing, puncture- and leak-proof container immediately after use.





SAFETY

The safety profile of EBGLYSS has been well studied.

In clinical studies, some people taking **EBGLYSS** had side effects.

Most of the side effects were mild-moderate in severity, and did not stop them continuing with treatment.

The most common side effects of **EBGLYSS** include:

- Eye and eyelid inflammation, including change in skin colour, swelling, and itching
- Injection site reactions
- Shingles (herpes zoster)
- High count of certain white blood cells (eosinophilia)



Inform your doctor or dermatology nurse promptly about any side effects that you experience.



Please carefully read the patient leaflet which describes possible side effects in detail.

THE IMPORTANCE OF STAYING ON TREATMENT

Taking medicines as advised by your healthcare professional is fundamental

Atopic eczema, like other chronic diseases, will likely require treatment over a long period of time.



Establish the goals of treatment with your dermatologist and make sure you attend your follow-up appointments. Make sure you ask your dermatologist or nurse about any doubts you have.

Finally, if remembering medication is a challenge for you, there are a number of ways to remind yourself.



There are many strategies that can help you take or apply your medication as your doctor prescribed it.

Early follow-up visits and short-term treatment goals

Nurse support Strategies to improve treatment adherence

Reminder programs

(emails, phone calls, text messages, smartphone applications etc)

Therapeutic education

(written action plans, use of drawings, photographs, videos, etc)

INFORMATION FOR FVFRYDAY LIFF WITH ATOPIC ECZEMA

Here are some lifestyle changes that dermatologists recommend to ease symptoms of atopic eczema:



Moisturise after bathing and when your skin feels dry. Keeping your skin hydrated helps form a barrier between you and the world. Use a fragrance-free emollient (medical moisturiser).



Choose fragrance-free skin care products. Fragrance can cause an atopic eczema flare-up. Use only products labelled "fragrance free" or "unscented".



Take short baths or showers to hydrate your skin. Limit your bath to 5-10 minutes and use warm water. Apply your moisturiser while your skin is still damp after bathing.



Wear loose-fitting 100% natural clothing. Cotton, silk and bamboo are less irritating than some other fibres and lets your skin breathe. To avoid flare-ups, avoid wearing tight clothing, and avoid wearing wool next to your skin.



Wash clothing in detergent that is free from fragrances, dyes and fabric softeners. These can all trigger a flare-up.



Wash new clothing before you wear it. Be sure to use a fragrance-free, dye-free detergent.



Wash your bedding at 60 degrees. The high temperature will destroy dust mites.



Protect your skin from extreme temperatures. Cold temperatures can dry your skin, which can cause a flare-up - but when you sweat, the sweat itself can also trigger a flare-up.

FAQ

What if I forget/miss an injection?

If you forget to take a dose, that dose should be administered as soon as possible. Thereafter, dosing should be resumed at the regular scheduled time.

Can **EBGLYSS** influence my ability to drive?

EBGLYSS is unlikely to influence your ability to drive and use machinery.

How long should I continue taking EBGLYSS?

You should continue the medication as long as your doctor tells you to. Do not stop without talking to them first.

Can I stop medication or change my dosing?

You will need to discuss any changes in dosing with your doctor.

Are there any foods I should avoid while taking EBGLYSS?

EBGLYSS is not known to interact with any foods. You do not need to change your diet while taking it.

Can I consume alcoholic beverages while taking **EBGLYSS**?

Alcoholic beverages can be consumed while taking **EBGLYSS**. However, reducing alcohol consumption is a good idea for anvone's overall health.

Are there any medications that I can/cannot take while on EBGLYSS?

Since **EBGLYSS** is a biologic treatment. no interactions with other drugs are known to date. Please ask your doctor if you have any concerns.

What if I become pregnant?

There is little research evidence on the use of **EBGLYSS** during pregnancy. Ask your doctor for specific advice, but it is likely that **EBGLYSS** should be avoided during pregnancy given the lack of relevant clinical data.

What if I am breastfeeding?

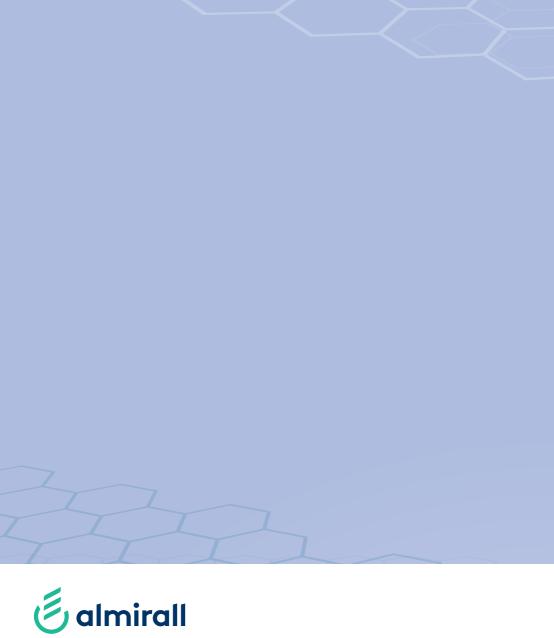
It is not known whether **EBGLYSS** can pass into breast milk. If you are breastfeeding or are planning to breastfeed, talk to your doctor before using it. You and your doctor should decide if you will breastfeed or use **EBGLYSS** You should not do both

Can I have a vaccination while taking EBGLYSS?

Your doctor will advise you about getting any vaccinations before or while taking **EBGLYSS**. However, prior to initiating therapy with **EBGLYSS**, it is likely your doctor may want you to complete all age-appropriate immunisations according to local guidance. Live and live attenuated vaccines should not be given at the same time as EBGLYSS.



Consult the EBGLYSS package leaflet for more information.





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