Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Adtralza 150 mg solution for injection in pre-filled syringe

tralokinumab

PLGB 05293/0182

LEO Pharma A/S

LAY SUMMARY

Adtralza 150 mg solution for injection in pre-filled syringe
tralokinumab

This is a summary of the Public Assessment Report (PAR) for Adtralza 150 mg solution for injection in pre-filled syringe. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Adtralza in this lay summary for ease of reading.

For practical information about using Adtralza, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Adtralza and what is it used for?

This product has been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). In coming to its decision, MHRA has relied on a European Commission (EC) decision on 17 June 2021 (EMEA/H/C/005255/0000), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). This is known as the EC Decision Reliance Procedure.

Adtralza is indicated for the treatment of adults with moderate-to-severe atopic dermatitis, also known as atopic eczema. Adtralza may be used with eczema medicines that you apply to the skin, or it may be used on its own.

This application was submitted as a national new active substance application via the EC Decision Reliance Route.

How does Adtralza work?

The active substance in Adtralza is tralokinumab, a humanised monoclonal antibody (mAb), a type of protein designed to recognise and attach to a specific target substance in the body. Tralokinumab blocks the action of a protein called interleukin-13 (IL-13). IL-13 plays a major role in causing the symptoms of atopic dermatitis.

How is Adtralza used?

The pharmaceutical form of this medicine is a solution for injection and the route of administration is subcutaneous injection.

The recommended dose of tralokinumab for adult patients is an initial dose of 600 mg (four 150 mg injections) followed by 300 mg (two 150 mg injections) administered every other week as subcutaneous injection.

Dose reduction is not recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability.

Dose adjustment is not required for the elderly, patients with renal or hepatic impairment. Adtralza is not recommended for use in paediatric population.

Adtralza is for subcutaneous use. Adtralza should be administered by subcutaneous injection into the thigh or abdomen. If the injection is not self-administered, the upper arm can also be used. It is recommended to rotate the injection site with each dose.

For further information on how Adtralza is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should ask the administering healthcare practitioner if they have any questions concerning the medicine.

What are the possible side effects of Adtralza?
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on behalf of someone else they care for, directly via the Yellow Card scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

The most common side effects with Adtralza (which may affect more than 1 in 10 people) were upper respiratory tract infections (i.e. common cold and sore throat).

Why was Adtralza approved?
MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

What measures are being taken to ensure the safe and effective use of Adtralza?
A Risk Management Plan (RMP) has been developed to ensure that Adtralza is used as safely as possible. Based on this plan, safety information has been included in the SmPC and the PIL, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Adtralza
A marketing authorisation was granted in Great Britain on 21 June 2021.

The full PAR for Adtralza follows this summary.

This summary was last updated in August 2021.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Adtralza 150 mg solution for injection in pre-filled syringe (PLGB 05293/0182) could be approved.

The product is approved for the following indication:
Treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy.

The name of the active substance is tralokinumab.

Tralokinumab is a fully human IgG4 monoclonal antibody that specifically binds to the type 2 cytokine interleukin-13 (IL-13) and inhibits its interaction with the IL-13 receptors. Tralokinumab neutralises the biological activity of IL-13 by blocking its interaction with the IL-13Rα1/IL-4Rα receptor complex. IL-13 is a major driver of human type 2 inflammatory disease, such as atopic dermatitis and inhibiting the IL-13 pathway with tralokinumab in patients decreases many of the mediators of type 2 inflammation.

This product has been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). In coming to its decision, MHRA has relied on a European Commission (EC) decision on 17 June 2021 (EMEA/H/C/005255/0000), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP).
For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the European Medicines Agency (EMA), please refer to the European Public Assessment Report, available on the EMA website.

This application was approved under Regulation 50 of the Human Medicines Regulation 2012, as amended (previously Article 8(3) of Directive 2001/83/EC, as amended).

In line with the legal requirements for children's medicines, the application included a licensing authority decision on the agreement of a paediatric investigation plan (PIP) (P/0145/2020).

At the time of the submission of the application the PIP was not yet completed as some measures were deferred.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and is satisfactory.

A Marketing Authorisation was granted on 21 June 2021.

II. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERITICS (SmPC)

The SmPC is in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET

The PIL is in line with current guidelines and is satisfactory.

LABEL
The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS
MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation is recommended.

IV. NON-CLINICAL ASPECTS
MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation is recommended.

V. CLINICAL ASPECTS
MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation is recommended.

VI. RISK MANAGEMENT PLAN (RMP)
The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION
A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application, in accordance with legal requirements.

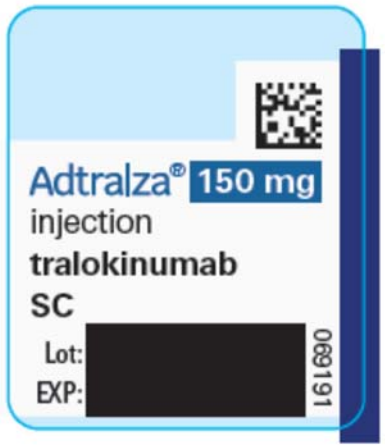
The PIL has been evaluated via a user consultation study in accordance with legal requirements. The results show that the PIL meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

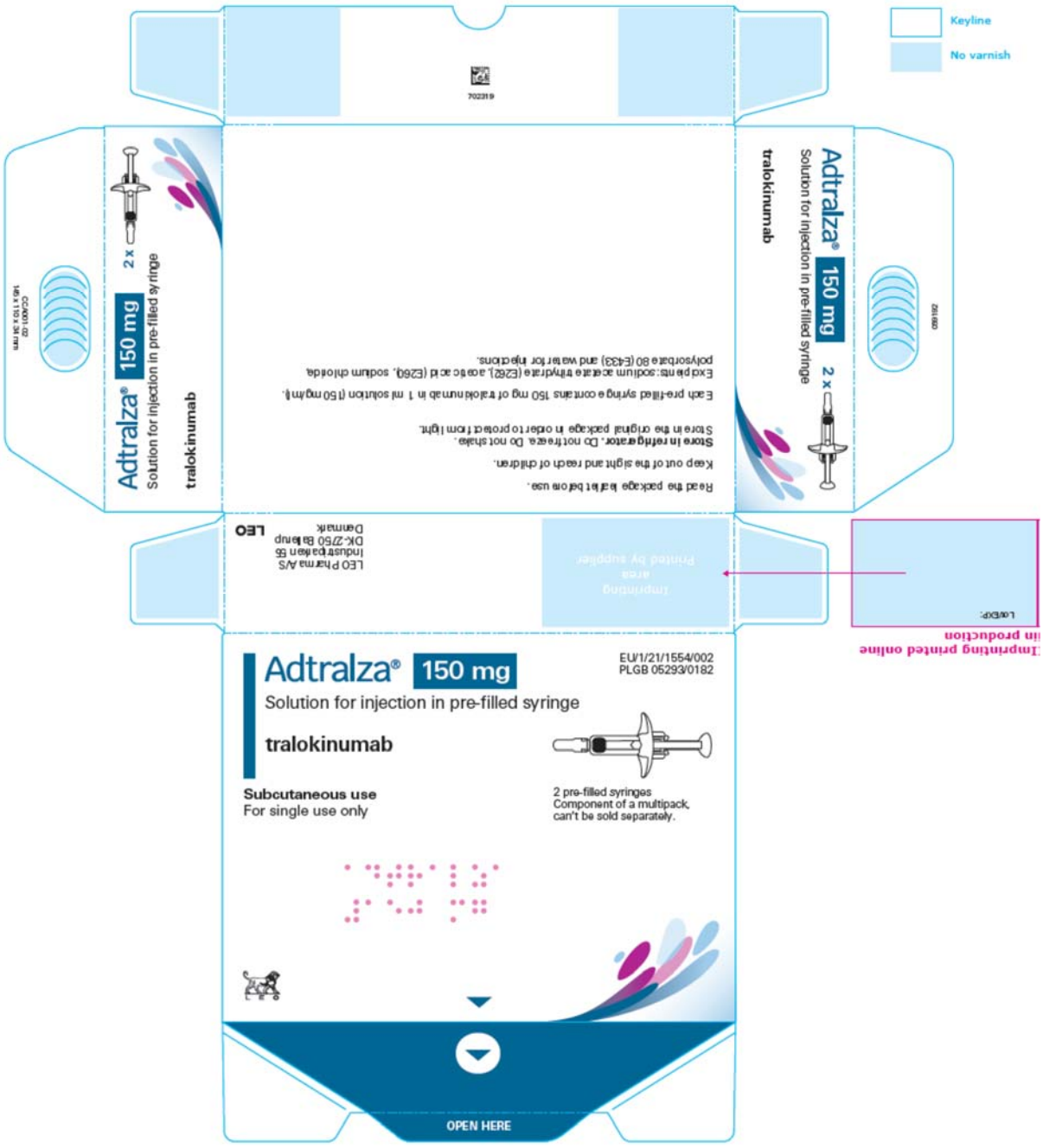
VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

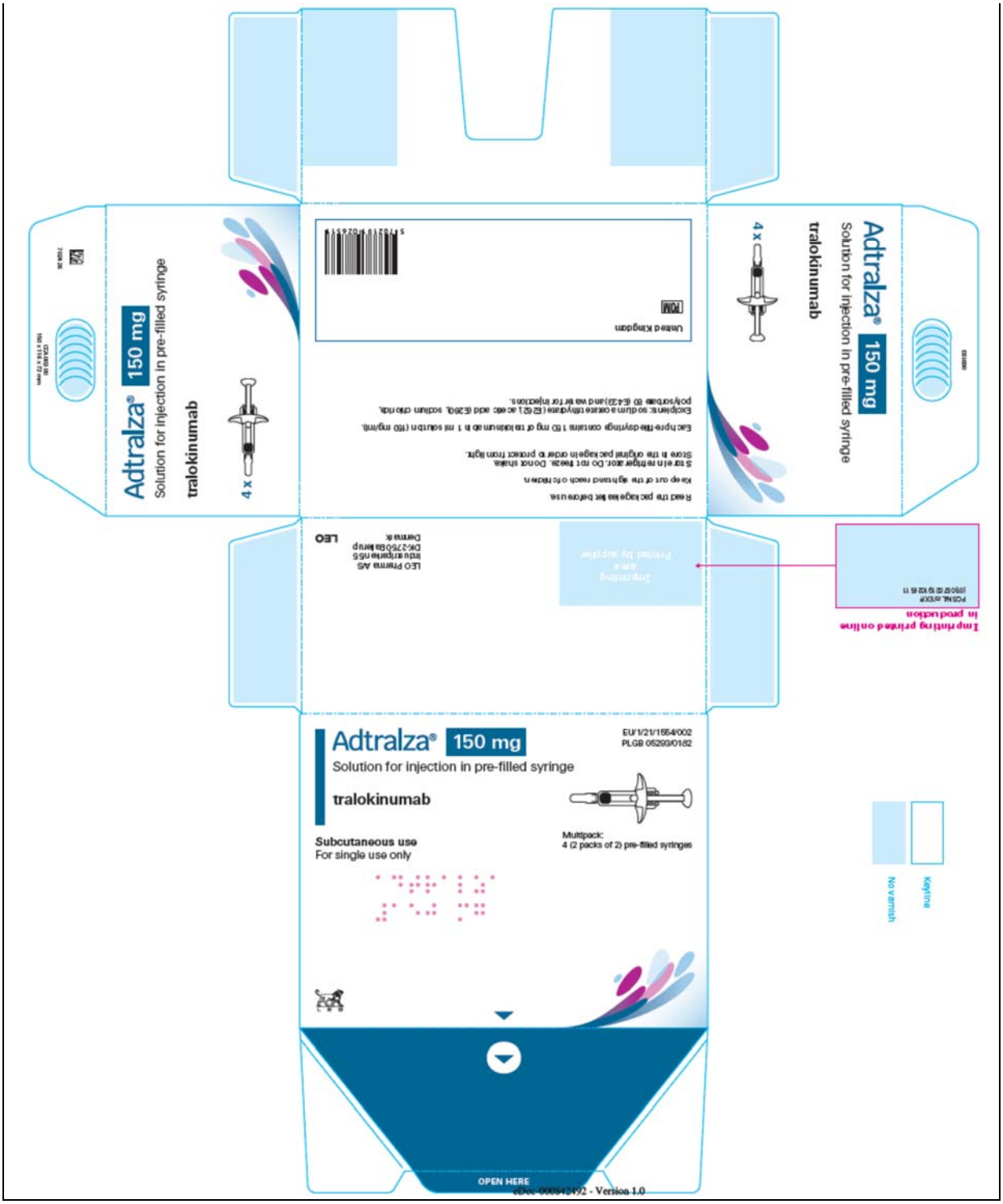
The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for these products are available on the MHRA website.

Representative copies of the labels at the time of UK licensing are provided below.


Adtralza® 150 mg
injection
tralokinumab
SC
Lot:
EXP:
069191


Keyline
No varnish
Adtralza® 150 mg
Solution for injection in pre-filled syringe
tralokinumab
2 x
Read the package leaflet before use.
Keep out of the sight and reach of children.
Store in refrigerator. Do not freeze. Do not shake.
Store in the original package in order to protect from light.
Each pre-filled syringe contains 150 mg of tralokinumab in 1 ml solution (150 mg/ml).
Excipients: sodium acetate trihydrate (E262), acetic acid (E260), sodium chloride, polysorbate 80 (E433) and water for injections.
LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark
LEO
Printing area
Printed by supplier
Imprinting printed online in production
EU/1/21/1554/002
PLGB 05293/0182
Adtralza® 150 mg
Solution for injection in pre-filled syringe
tralokinumab
Subcutaneous use
For single use only
2 pre-filled syringes
Component of a multipack, can't be sold separately.
OPEN HERE


Adtralza® 150 mg
Solution for injection in pre-filled syringe
tralokinumab
4 x
Adtralza® 150 mg
Solution for injection in pre-filled syringe
tralokinumab
4 x
United Kingdom
LEO
Adtralza® 150 mg
Solution for injection in pre-filled syringe
tralokinumab
EU/1/21/1554/002
PLGB 05293/0182
Subcutaneous use
For single use only
Multipack:
4 (2 packs of 2) pre-filled syringes
Keyline
No varnish
OPEN HERE

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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**