



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 hours
Pharmacy/Wholesaler Level Recall

Date: 21 February 2024

EL (24)A/06

Our Ref: MDR 183-01/24

Dear Healthcare Professional,

Novartis Pharmaceuticals UK Limited

Adakveo 10 mg/ml concentrate for solution for infusion

PLGB 00101/1191

SNOMED Code 39653911000001104

Batch No	Expiry Date	Pack Size	First Distributed
SJFN5	30/09/2024	1 vial	23/05/2023

Active Pharmaceutical Ingredient: crizanlizumab

Brief description of the problem

Novartis Pharmaceuticals UK Limited is recalling Adakveo 10 mg/ml concentrate for solution for infusion, batch number SJFN5, due to the benefit-risk balance of Adakveo no longer being considered favourable by the MHRA. This is because the Phase III study (STAND) of Adakveo in sickle cell disease patients with vaso-occlusive crises did not confirm its clinical benefit. As a consequence, the conditional marketing authorisation in the UK is being revoked.

Advice for healthcare professionals

Stop supplying the above batch immediately. Quarantine all remaining stock and await contact from the Novartis Pharmaceuticals UK Limited customer care team who will contact healthcare professionals directly to arrange return. Novartis Pharmaceuticals UK Limited have a direct to pharmacy supply chain agreement based on the specialist use of the product and know the exact hospitals who have been supplied with the impacted batch.

- Clinicians and prescribers who initiated patients on Adakveo 10 mg/ml concentrate for solution for infusion should inform patients of the licence revocation and discuss alternative treatment options with them. No new patients should be started on Adakveo in the UK.
- Healthcare professionals who receive any questions from patients related to the recall notice should advise patients undergoing treatment to discuss any questions or concerns with their prescribing healthcare professional. No new patients should be started on Adakveo in the UK.

A Dear Healthcare Professional Letter (DHPC) was sent on 10 January 2024 announcing the revocation of Adakveo by Novartis Pharmaceuticals UK Limited.

- See full text link for the DHPC: <https://www.medicines.org.uk/emc/dhpc/2874/Document>



Medicines & Healthcare products Regulatory Agency

Advice for patients

Patients currently prescribed Adakveo 10 mg/ml concentrate for solution for infusion will be contacted by their prescribing healthcare professional. This is because you require a review with your prescribing healthcare professional to discuss alternative treatment options. Do not stop administering Adakveo without talking to your prescribing healthcare professional.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please contact Novartis Pharmaceuticals UK Limited at: <https://www.novartis.com/uk-en/contact/contact-us>, by email: medinfo.uk@novartis.com or via telephone: +44 1276 698370.

For stock control enquiries please contact: commercial.team@novartis.com

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk