Kingdome of Saudi Arabia

27-05-2024

Direct Healthcare Professional Communication letter

Cablivi (Caplacizumab) – Approval for shelf-life extension of current stocks available in Kingdome of Saudi Arabia from 48 months to 60 months

Dear Healthcare Professional,

Sanofi in agreement with the Saudi Food and Drug Authority, would like to inform you about a change for Cablivi (caplacizumab) with the intention to extend the drug product (DP) shelf life from 48 to 60 months. The variation to extend the product shelf-life has been approved by Saudi Food and Drug Authority on 1st of April 2023.

Summary:

Sanofi would like to inform you that in April 2023, Saudi Food and Drug Authority has approved to extend the drug product shelf life from 48 to 60 months for Cablivi.

And in 18th of Jun 2023, Sanofi received the approval to sticker the batch A0A82200A with the new shelf-life from Saudi Food and Drug Auhtority.

Further information on the Safety concerns:

Cablivi is approved for treating adults who have experienced an episode of acquired thrombotic thrombocytopenic purpura (aTTP) in conjunction with plasma exchange and immunosuppression. Acquired thrombotic thrombocytopenic purpura (aTTP) is a rare blood clotting disorder that if untreated can lead to patient death.

As part of our commitment to ensure the availability of this life-saving medication to patients, we would like to inform you that the shelf-life of the enclosed batches for Cablivi below has been extended based on stickering approval from **Saudi Food and Drug Authority** of the current stocks, dated 18 Jun 2023.

It has been confirmed by the manufacturing site that the current batches can be extended as per the below mentioned extended expiry dates and are valid for use where the quality and safety of the medication remains **unchanged.**

This letter is reviewed and approved by SFDA.

Product description	Batch number	Current expiry date	Extended Expiry date
Cablivi 10 MG Powder and Solvent for Solution for Injection	A0A82200A	01/31/2024	31-01-2025

As Sanofi does not perform re-labelling of the packaging locally, this letter is intended to notify you on the stickering of the new expiry date of the batches available in the market.

Cablivi is a hospital use medication only administered under supervision by the Healthcare Professional in a **hospital setting only.**

Call for reporting

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

For Saudi Arabia

The National Pharmacovigilance Centre (NPC):

- SFDA call center : 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa/
- QR Code

Sanofi Saudi Arabia PV department

- +966-54-428-4797
- KSA_Pharmacovigilance@sanofi.com

Should you have any question or require additional information, please call Medical Information at:

Medical Information

- +966-12-669-3318
- ksa.medicalinformation@sanofi.com

Mossab Shafy

Country Safety Head & Local QPPV

This letter is reviewed and approved by SFDA.