

Direct Healthcare Professional Communication

28th June 2019

Cerliponase Alfa (Brineura▼): Temporary Change in Packaging

Dear Healthcare professional,
BioMarin International Limited would like to inform you of the following:

Summary

- English-language UK packs of Brineura will be temporarily unavailable until the end of August 2019
- Following agreement from the MHRA, Brineura packaged for the German market will be provided to treating physicians in the interim; German-packaged Brineura units are of the same quality, composition and formulation as the UK units
- An English Patient Leaflet will accompany each unit shipped

Background

Brineura is indicated for the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency.

Brineura was provided commercially as a multi-region presentation, with packaging covering UK, Germany, Austria, France, Denmark, and The Netherlands. However, because of BioMarin's Brexit planning activities, the UK pack has been de-coupled from this original launch presentation.

Delays in the implementation of the new, stand-alone UK packs, and unforeseen increase in demand for the current multi-region pack, have led to a shortage in the supply chain.

The replacement German packaged Brineura units are of the same quality, composition and formulation as the UK units – there is no difference in the drug product quality being released, except for the language of the text on the carton and patient leaflets.

Call for reporting

This medicinal product is subject to additional monitoring.

Reporting suspected adverse reactions after authorisation 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 through the Yellow Card Scheme Website: <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

For biological medicinal products such as Brineura, please also remember to report the product name and batch details.

Company contact point

For access to further information, please email: medinfo@bmrn.com

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