octapharma

PRODUCT INFORMATION UPDATE FOR HEALTHCARE PROFESSIONALS

CUTAQUIG, 165mg/ml, solution for injection (PA2219/001/001)
Updated information on infusion rates

12th September 2023

Dear Healthcare Professional,

We are writing in connection with a recent update to the Summary of Product Characteristics (SmPC) for **CUTAQUIG, 165mg/ml, solution for injection** following a recent study which evaluated different dosage regimes in primary immunodeficiency (PID) patients, including an increased infusion volume and increased infusion flow rates. Based on the final data of the study, the information on infusion rates in Section 4.2 of the SmPC for CUTAQUIG has been updated to the following:

"Infusion rate
Adjustment of the infusion rate and infusion volume per site is based on subject tolerability.

It is recommended to use an initial administration rate of 15 ml/h/**site for patients naïve on SCIG therapy. For patients already on SCIG therapy and switching to Cutaquig it is recommended to use previously used administration rates for the initial infusions. For subsequent infusions,** if well tolerated (see section 4.4), the infusion rate can be gradually increased by approximately 10 ml/h/site every 2-4 weeks in adults (≥ 40 kg) and up to 10 mL/h/site every 4 weeks for paediatrics (<40 kg) (see section 5.1).

Thereafter, if the patient tolerates the initial infusions at the full dose per site and maximum rate, an increase in the infusion rate of successive infusions may be considered until reaching a maximum flow rate of 67.5 ml/h/site for adults and 25 ml/h/site for pediatrics (see section 5.1).

More than one infusion device can be used simultaneously. "

In addition to this communication, the updated product information for CUTAQUIG is available on medicines.ie and on the HPRA website:

https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results/item?pano=PA2219/001/001&%20165%20mg/ml,%20solution%20for%20injection

Octapharma Limited
Glassworks House
32 Shudehill
Manchester
M4 1EZ

Office: +44 (0)161 837 3770
Fax: +44 (0)161 837 3799
Email: customerservices.uk@octapharma.com
Web: www.octapharma.co.uk

Registered in England No. 2372699
VAT No GB 585216330

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the HPRA via the HPRA website.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies, and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product license number and manufacturer), and the specific batch number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to report suspected ADRs more accurately to the HPRA.

Company contact point

This communication is provided jointly from the Marketing Authorisation Holder (MAH) and local agent in the Republic of Ireland and has been agreed with the HPRA.

MAH: Octapharma (IP) SPRL, Allee de la Recherche 65, 1070 Anderlecht, Belgium
Local agent: Octapharma Ltd, Glassworks House, 32 Shudehill, Manchester, M4 1EZ, United Kingdom.

Should you have any questions about this letter or require more information about CUTAQUIG, please contact Octapharma Ltd Medical Information by email on uk.medinfo@octapharma.com, or visit www.octapharma.co.uk.

Yours faithfully

Karen Haworth-Shaw
Scientific Service Manager

On behalf of Octapharma Limited