20 May 2021
EMA/289188/2021
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): panitumumab

Procedure No. EMEA/H/C/PSUSA/00002283/202009

Period covered by the PSUR: 29 September 2019 – 29 September 2020

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for panitumumab, the scientific conclusions of CHMP are as follows:

In view of available data on medication errors, the PRAC concluded that the product information of products containing panitumumab should be amended accordingly.

The text regarding the handling of panitumumab should be amended to include information regarding the filter, as already included in Section 4.2, 'Method of administration' of the Summary of Product Characteristics and the Package Leaflet.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for panitumumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing panitumumab is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.