31 January 2019
EMA/227269/2019
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): dasatinib

Procedure No. EMEA/H/C/PSUSA/00000935/201806

Period covered by the PSUR: 28 June 2017 – 27 June 2018

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Scientific conclusions

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

A causal relationship between discontinuation of dasatinib therapy and withdrawal syndrome was confirmed, based on the musculoskeletal withdrawal symptoms at incidence rate of 9.5% in study DASFREE. The PRAC considers that the product information of dasatinib containing products should be amended to reflect the risk of musculoskeletal pain associated with discontinuation of dasatinib therapy. As the risk has already been identified for imatinib and nilotinib, it is considered a potential subclass effect for BCR/ABL targeting tyrosine kinase inhibitors (TKIs).

A causal relationship between thrombotic microangiopathy and dasatinib is considered possible based on the evidence from eight cases of thrombotic microangiopathy associated with dasatinib treatment. Given the presented evidence, the PRAC considers thrombotic microangiopathy an important potential risk for dasatinib and the product information of dasatinib containing products should be amended to reflect this risk. Also, based on the evidence in the literature, thrombotic microangiopathy is considered as a potential subclass effect for BCR/ABL-targeting TKIs.

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 dasatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dasatinib 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.