



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 September 2019  
EMA/CHMP/PRAC/501568/2019  
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): ferric maltol

Procedure No. EMEA/H/C/PSUSA/00010476/201808

Period covered by the PSUR: 17 August 2018 To: 17 February 2019



**Scientific conclusions**

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

Faeces discolouration was observed in patients treated with ferric maltol in clinical trials. Black discolouration of the stool is a well-known ADR of oral iron formulations. The PRAC concluded that the product information of products containing ferric maltol should be amended accordingly.

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