

Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

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

There were respectively 3 and 140 cases of chromaturia reported during the reporting period and cumulatively. Urine coloration is a known effect of diacerein that may be mistaken with haematuria leading to further unnecessary medical procedures.

Based on the information presented in this PSUR, PRAC considered that section 4.8 of the Summary of Product Characteristics should be amended to include chromaturia with a frequency unknown.

The CMDh 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 diacerein, the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing diacerein is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing diacerein are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.8

The following adverse reaction should be added under the SOC Renal and urinary disorders with a frequency unknown:

Chromaturia

Package Leaflet

- Section 4 Possible side effects

The following adverse reaction should be added with a frequency unknown:

Discoloration (darkening) of urine. If you are concerned, check with your doctor.

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	September 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	28 October 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 December 2017