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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: collagenase clostridium histolyticum

Procedure No. EMEA/H/C/PSUSA/00000871/201402

Period covered by the PSUR: 28 August 2013 – 27 February 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for collagenase clostridium histolyticum, the scientific conclusions of CHMP are as follows:

A higher rate for skin laceration has been reported following two concurrent injections in the same hand. This result should be included in section 4.4 of the SmPC. Information regarding serious skin lacerations requiring skin graft should also be added to section 4.4 of the SmPC.

In addition, following reports of tendon/ligament injuries, section 4.4 of the SmPC should be updated to include the information on the higher risk of tendon/ligament damage for patients where Xiapex is injected in the proximal interphalangeal (PIP) joint of the fifth finger.

No changes to the package leaflet, labelling or Annex II are deemed necessary.

The educational material and physician training should be updated accordingly.

Therefore, in view of available data regarding collagenase clostridium histolyticum, the PRAC considered that changes to the product information were warranted. The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for collagenase clostridium histolyticum the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing collagenase clostridium histolyticum is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation should be varied.