



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 September 2015
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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/00000871/201502

Period covered by the PSUR: 28 February 2014 – 27 February 2015

Medicinal product no longer authorised



Scientific conclusions

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

In the cumulative and interval summary tabulations there are 17 new cases of fracture of penis provided for this post-marketing PSUR period. In addition there are one serious and 13 non-serious cases of penile haemorrhage. Furthermore 30 additional non-serious adverse events of penile haematoma have been provided post-marketing for this reporting period. Post-marketing cases of penis rupture compared to the patient's numbers exposed to the product are in line with the results from clinical studies.

However, traumatic rupture of the penis is relatively uncommon; patients with Peyronie's disease are theoretically at greater risk of corporal rupture, which is considered a urologic emergency typically requiring surgical intervention. Although corporal rupture is not life threatening or fatal it might have a high impact on patients quality of life, especially if followed by sequelae, which were not seen in the clinical studies, however, cannot be excluded. Hence, amendments to the product information to highlight the importance of the adverse event penis fracture and the need for surgical intervention are considered necessary.

Therefore, in view of available data regarding fracture of the penis 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.