1 April 2016
EMA/391817/2016
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): glimepiride / pioglitazone hydrochloride, metformin / pioglitazone, pioglitazone

Procedure No. EMEA/H/C/PSUSA/00002417/201507

Period covered by the PSUR: 01 August 2014 to 31 July 2015

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for glimepiride / pioglitazone hydrochloride, metformin / pioglitazone, pioglitazone, the scientific conclusions of CHMP are as follows:

The product information (Sections 4.4 and 4.8 of the SmPC) provides already information on clinical trial results in which showed an increased fracture risk in women only. However epidemiological data from the post-marketing experience shows an increased risk of fractures in both men and women and caution is advised in patients with long term treatment. Therefore it is recommended that the product information for pioglitazone-containing products is updated to accurately reflect the post-marketing experience in the relevant sections of the SmPC and the package leaflet.

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 glimepiride / pioglitazone hydrochloride, metformin / pioglitazone, pioglitazone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing glimepiride / pioglitazone hydrochloride, metformin / pioglitazone, pioglitazone 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.