19 September 2013
EMA/CHMP/538715/2013
Committee for Medicinal Products for Human Use

Ipreziv

International non-proprietary name: azilsartan medoxomil

Procedure No. EMEA/H/C/002517/PSUV/0008

Period covered by the PSUR: 25 August 2012 to 24 February 2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for Edarbi and Ipreziv, the scientific conclusions of PRAC are as follows:

In the current Summary of Product Characteristics (SmPC) the following statement is included below the adverse drug reactions (ADR) table in section 4.8: 'Angioedema, including circumoral oedema and periorbital oedema, was rarely seen in patients during open label treatment with Edarbi/Ipreziv'. Based on the fact that angioedema is a well-known class effect of Angiotensin II Receptor Blockers (ARBs), angioedema has been reported for azilsartan and has been assessed as being related to azilsartan medoxomil the PRAC considers that the adverse drug reaction 'angioedema' should be included in the ADR table (SmPC section 4.8) under the system organ class (SOC) 'Skin and subcutaneous disorders'. In addition the frequency 'rare' should be assigned based on a single case observed in a subject exposed to azilsartan medoxomil during the clinical trial program.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisations

On the basis of the scientific conclusions for Edarbi and Ipreziv the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing the active substance azilsartan medoxomil is favourable subject to the proposed changes to the product information.

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