EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/719950/2013
Committee for Medicinal Products for Human Use (CHMP)

Silodyx

International non-proprietary name: silodosin

Procedure No. EMEA/H/C/001209/PSUV/0013

Period covered by the PSUR: 31-07-2012 – 30-01-2013

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 Urorec and Silodyx, the scientific conclusions of the PRAC are as follows:

In view of available data regarding silodosin, the PRAC considered that changes to the product information were warranted. The ADRs and frequencies proposed by the MAH and endorsed by the PRAC (Allergic-type reactions including facial swelling, swollen tongue and pharyngeal oedema, Loss of consciousness, Hypotension). However, the PRAC considers these ADRs and those currently included under a heading of 'adverse reactions from spontaneous reporting' should be included in the table of ADRs with a suitable footnote to explain that these have been reported post-marketing and are included (Tachychardia, Palpitations, Abnormal liver function tests, Skin rash, Pruritus, Urticaria, Drug eruption). A footnote is added to explain that these reactions were reporting post-marketing and that frequencies have been calculated based on events reported in phase I-IV clinical trials and non-interventional studies. The proposal to update the beginning of section 4 of the package leaflet with information on the risk of allergic reactions and need for patients to contact their doctor if these occur is endorsed.

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 Urorec and Silodyx the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing the active substance silodosin is favourable subject to the proposed changes to the product information.

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