30 January 2025
EMA/21627/2025
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): tolvaptan (indicated for adults with autosomal dominant polycystic kidney disease (ADPKD))

Procedure No. EMEA/H/C/PSUSA/00010395/202405

Period covered by the PSUR: 17/05/2021 To: 17/05/2024

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for tolvaptan (indicated for adults with autosomal dominant polycystic kidney disease (ADPKD)), the scientific conclusions of PRAC are as follows:

In view of available data on the risk of blood creatine phosphokinase (CPK) increased from the literature, spontaneous reports including in some cases a close temporal relationship and a positive de-challenge, the PRAC considers a causal relationship between tolvaptan (indicated for adults with autosomal dominant polycystic kidney disease (ADPKD)) and CPK increase is at least a reasonable possibility. The PRAC concluded that the product information of products containing tolvaptan (indicated for adults with ADPKD should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for tolvaptan (indicated for adults with autosomal dominant polycystic kidney disease (ADPKD)) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tolvaptan (indicated for adults with autosomal dominant polycystic kidney disease (ADPKD)) 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.