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Questions and answers on Furosemide Vitabalans (tablet, 40 mg)

Outcome of a procedure under Article 29 of Directive 2001/83/EC

On 18 October 2012, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Furosemide Vitabalans. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Furosemide Vitabalans do not outweigh its risks, and the marketing authorisation cannot be granted in Estonia and in the following Member States of the EU: Czech Republic, Denmark, Finland, Hungary, Latvia, Lithuania, Poland, Slovakia, Slovenia and Sweden, as well as Norway.

After re-examination, the Committee confirmed these recommendations on 18 February 2013.

What is Furosemide Vitabalans?

Furosemide Vitabalans is a medicine that contains the active substance furosemide. It was to be available as tablets (40 mg). The active substance in Furosemide Vitabalans, furosemide, belongs to a group of medicines known as diuretics. It works in the kidneys by increasing urine output, reducing the amount of fluid in the blood and lowering the blood pressure.

Furosemide Vitabalans was intended to be used to treat the following conditions:

- oedema (swelling) associated with congestive heart failure (a type of heart disease);
- cirrhosis of the liver (a type of liver disease) and renal disease, including nephrotic syndrome;
- mild to moderate hypertension (high blood pressure).

Why was Furosemide Vitabalans reviewed?

Vitabalans Oy submitted an application for Furosemide Vitabalans to the Estonian medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Estonia) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Czech Republic, Denmark, Finland, Hungary, Latvia, Lithuania, Norway, Poland, Slovakia, Slovenia and Sweden).

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However, the Member States were not able to reach an agreement and the Polish medicines regulatory agency referred the matter to the CHMP for arbitration on 30 May 2011.

The Polish and Lithuanian agencies were of the opinion that the data submitted to support the application did not provide sufficient evidence to demonstrate the safety and effectiveness of Furosemide Vitabalans. The application was supported by published literature rather than studies carried out with Furosemide Vitabalans, because furosemide has a history of well-established use in the EU for at least 10 years. The grounds for the referral were that the data from the literature submitted to support this application could not be applied to Furosemide Vitabalans and the bridging data provided were not considered adequate to conclude on the benefit-risk profile of Furosemide Vitabalans.

What are the conclusions of the CHMP?

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the data submitted were not sufficient to show that Furosemide Vitabalans could be used safely and effectively based on the well established use of furosemide. The CHMP concluded that the balance of the benefits and risks of Furosemide Vitabalans could not be established, and therefore the marketing authorisation for Furosemide Vitabalans should not be granted in all concerned Member States.

The CHMP confirmed the above conclusions after re-examining its opinion.

The European Commission issued a decision on 14 May 2013.