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Questions and answers on Galantamine Stada and associated names (galantamine 8, 16 and 24 mg prolonged released tablets)

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

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Galantamine Stada. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Galantamine Stada do not outweigh its risks, and the marketing authorisation cannot be granted in Austria or in other Member States of the EU: Czech Republic, Denmark, Finland, Ireland, Portugal, Slovakia and Spain.

What is Galantamine Stada?

Galantamine Stada is a medicine that contains the active substance galantamine. It is used to treat symptoms of mild to moderately severe Alzheimer's dementia, a progressive brain disorder that gradually affects memory, intellectual ability and behaviour.

In patients with Alzheimer's disease, certain nerve cells die in the brain, resulting in low levels of the neurotransmitter acetylcholine (a substance that allows nerve cells to communicate with each other).Galantamine works by blocking acetylcholinesterase, an enzyme that breaks down acetylcholine. By blocking this enzyme, galantamine allows levels of acetylcholine to be increased in the parts of the brain associated with intellectual function. This leads to improvement in the patient's symptoms.

Galantamine Stada is a generic medicine based on a 'reference medicine', Reminyl.

Why was Galantamine Stada reviewed?

Alfred E. Tiefenbacher GmbH & Co KG submitted Galantamine Stada to the Austrian medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Austria) 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 the Czech Republic, Denmark, Estonia, Finland, Ireland, Portugal, Slovakia and Spain).

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However, the Member States were not able to reach an agreement and the Czech Republic referred the matter to the CHMP for arbitration on 26 March 2010.

The grounds for the referral were that bioequivalence studies, to show that Galantamine Stada produces the same levels of active substance in the body as Reminil, had not been conclusive.

What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that bioequivalence to the reference medicinal product has not been shown. The CHMP therefore concluded that the benefits of Galantamine Stada do not outweigh its risks and recommended that the marketing authorisation should not be granted in the concerned Member States.

Following the CHMP opinion on 23 September 2010, the Agency was informed on 15 October 2010 that the company withdrew the applications for marketing authorisation in all concerned Member States.

The European Commission issued a decision on this referral on 21 February 2011.