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Questions and answers on Merisone and Myoson (tolperisone, 50 and 150 mg tablets)

Outcome of procedures under Article 29(4) of Directive 2001/83/EC

On 23 April 2015, the European Medicines Agency completed two arbitration procedures following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicines Merisone and Myoson (tolperisone). The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Merisone and Myoson outweigh their risks, and the marketing authorisation granted in Hungary can be recognised in other Member States of the EU.

What are Merisone and Myoson?

Merisone and Myoson are identical medicines that are used to treat muscle spasms (involuntary contractions) and spasticity.

The active substance in Merisone and Myoson, tolperisone, is a centrally acting muscle relaxant. The exact way tolperisone works is not known, but it is thought to act in the brain and spinal cord to reduce the nerve impulses that make the muscles contract and become rigid. By reducing these impulses, tolperisone is believed to reduce muscle contraction and spacticity.

Merisone and Myoson are generic medicines based on a 'reference medicine', Mydeton, which is already authorised in the EU.

Why were Merisone and Myoson reviewed?

Meditop Pharmaceutical Co. Ltd. submitted Merisone and Myoson for mutual recognition on the basis of their initial authorisation granted by Hungary on 18 March 2010. The company wanted the authorisation to be recognised in Belgium, Germany, Luxembourg and the Netherlands (the 'concerned Member States').

However, the Member States were not able to reach an agreement and the German and Dutch medicines regulatory agencies referred the matter to the CHMP for arbitration on 24 December 2014.

Because Merisone and Myoson are generic medicines, studies have been limited to tests to determine that they are bioequivalent to the reference medicine, Mydeton. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

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The grounds for the referral were that the bioequivalence studies had only been performed under fasting conditions. As the product information for Mydeton was recently updated to say that it should be taken with food, Germany and the Netherlands considered that a bioequivalence study under fed conditions would be required for the granting of a marketing authorisation.

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 because of the characteristics of the active substance of Merisone and Myoson food will affect the absorption of the active substance in the same way as for Mydeton and no further studies are required. The CHMP therefore concluded that in the case of Merisone and Myoson the bioequivalence study in the fasting state is sufficient to conclude on the bioequivalence in both the fasting and fed states and that the benefits and risks of Merisone and Myoson can be taken to be the same as the reference medicine's. The CHMP therefore recommended that the marketing authorisation be granted in the concerned Member States.

The European Commission adopted a decision on this opinion on 25 June 2015.