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Questions and answers on Canazole (clotrimazole cream 1%)

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 Canazole. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Canazole do not outweigh its risks, and the marketing authorisation granted in Ireland cannot be recognised in other Member States of the EU. The marketing authorisation in Ireland should also be suspended.

What is Canazole?

Canazole is a cream that contains the active substance clotrimazole (1%). It is used to treat skin infections caused by fungi, such as thrush, ringworm or athlete's foot.

The active substance in Canazole, clotrimazole, is an antifungal medicine that belongs to the group called triazoles. It works by preventing the formation of ergosterol, which is an important part of fungal cell walls. Without ergosterol, the fungus is killed or prevented from spreading.

Canazole is a generic medicine based on a 'reference medicine', Canesten, which is authorised in the United Kingdom.

Why was Canazole reviewed?

Pinewood Laboratories Ltd submitted Canazole for mutual recognition on the basis of the initial authorisation granted by Ireland on 8 December 2000. The company which recently marketed this product wanted the authorisation to be recognised in the United Kingdom (the 'concerned Member State'). However, the Member States were not able to reach an agreement and the Irish medicines regulatory agency referred the matter to the CHMP for arbitration on 25 November 2010.

The grounds for the referral were that the United Kingdom did not agree that Canazole cream and Canesten cream are similar enough to have therapeutic equivalence.

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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 the currently available data were not sufficient to show therapeutic equivalence with the reference medicine and that further data would need to be generated. The CHMP therefore concluded that the benefits of Canazole do not outweigh its risks and recommended that the marketing authorisation should not be granted in the concerned Member State. In addition, the Committee has also recommended that the marketing authorisation for Canazole in Ireland be suspended until further studies are done.

The European Commission issued a Decision on 22 September 2011.