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Veterinary Medicines Division

Questions and answers on Adjusol trimethoprim sulfa liquide and its associated names

Outcome of a referral procedure under Article 34 of Directive 2001/82/EC (EMEA/V/A/134)

On 10 December 2020, the European Medicines Agency (the Agency) completed a review of Adjusol trimethoprim sulfa liquide and its associated names. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that there is a need to harmonise the product information [summary of product characteristics (SPC), labelling and package leaflet] for the aforementioned product in the European Union (EU).

What is Adjusol trimethoprim sulfa liquide and its associated names?

Adjusol is a veterinary medicine available as a solution for use in drinking water or milk containing sulfadiazine and trimethoprim as active substances. Sulfadiazine and trimethoprim are antimicrobials which, when used separately, work by preventing bacteria from growing, but do not kill them. They are often used together because when their effects are added, the combination can kill bacteria. This veterinary medicine is used to treat infections caused by bacteria in calves, lambs, pigs, rabbits and chickens.

Adjusol is marketed in France, Greece, Luxembourg, and Portugal.

Why was Adjusol reviewed?

Adjusol is authorised in the EU via national procedures. This has led to inconsistency across Member States in the way the veterinary medicine can be used, as seen in the differences in the product information in the countries where Adjusol is marketed.

On 8 July 2019, the European Commission referred the matter to the CVMP in order to harmonise the product information for Adjusol in the EU.

What are the conclusions of the CVMP?

Based on the evaluation of the currently available data, the CVMP concluded by consensus that the product information for Adjusol should be harmonised across the EU.

The amended product information is available on the 'All documents' tab.

The European Commission issued a decision on 25 February 2021.

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