EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 March 2015
EMA/CVMP/156049/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

DRAXXIN

International non-proprietary name (INN): Tulathromycin

On 12 March 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted an opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product DRAXXIN. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

The variation agreed by the CVMP concerns the change to the withdrawal periods for cattle and pigs affecting all registered DRAXXIN presentations (EU/2/03/041/001-008), following the revision of MRLs for tulathromycin. The withdrawal periods for swine and cattle are amended from 33 days to 13 days and from 49 days to 22 days, respectively.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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