

22 April 2016
EMA/CVMP/231759/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

Aivlosin

International non-proprietary name (INN): tylvalosin

On 21 April 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Aivlosin. The marketing authorisation holder for this veterinary medicinal product is Eco Animal Health Ltd.

Aivlosin 625 mg/g granules for use in drinking water is currently not authorised for use in birds producing eggs for human consumption, and not to be used in chickens within 14 days of onset of lay.

This variation concerns a change in the withdrawal period for chicken eggs. As a consequence, the product can now be used in laying hens, for the treatment and metaphylaxis of respiratory infections caused by *Mycoplasma gallisepticum*.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes 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.