25 May 2020
EMA/CVMP/238731/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Aivlosin

International non-proprietary name (INN): tylvalosin

On 20 May 2020, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], 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 Europe Limited.

Aivlosin granules for use in drinking water are currently authorised for use in pigs for the "Treatment and metaphylaxis of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis"*. This variation is to add a new indication to this formulation for "Treatment and metaphylaxis of swine enzootic pneumonia caused by susceptible strains of *Mycoplasma hyopneumoniae*". As a consequence, changes to the dosage have been made, and the withdrawal period has been increased to 2 days, these changes will also apply to the already authorised indication for Aivlosin granules for use in drinking water for pigs.

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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union