

19 January 2018 EMA/CVMP/834159/2017 Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

Panacur AquaSol

International non-proprietary name (INN): fenbendazole

On 18 January 2018, 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 Panacur AquaSol. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Panacur AquaSol is currently authorised as an oral suspension. The variation concerns the addition of a new therapeutic indication (*Capillaria* spp. L5 and adult stages) in chickens and the modification of the withdrawal period.

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.

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.



¹ Summaries of opinion are published without prejudice to the Commission Decision.