16 March 2018
EMA/CVMP/121944/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Activyl Tick Plus

International non-proprietary name (INN): indoxacarb / permethrin

On 15 March 2018, 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 Activyl Tick Plus. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Activyl Tick Plus is currently authorised as a spot-on solution. The variation concerns the change of the legal status of this veterinary medicine from prescription-only to non-prescription. Additional editorial changes in the product information were implemented with the purpose to align with QRD template v.8.1 and similar products, or to further increase the readability and clarity for the non-professional user in order to mitigate the risk of erroneous use and to safeguard user and animal safety.

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.

Medicinal product no longer authorised

[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

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