22 April 2016
EMA/CVMP/213655/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Sevocalm

International non-proprietary name (INN): sevoflurane

On 21 April 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Sevocalm, 100% v/v inhalation vapour, liquid, intended for the induction and maintenance of anaesthesia in dogs. The applicant for this veterinary medicinal product is Chanelle Pharmaceuticals Manufacturing Limited.

Sevocalm is an inhalation anaesthetic containing 100% v/v sevoflurane (ATCvet code QN01AB08) as the active substance.

The benefits of Sevocalm are rapid induction and change in depth of anaesthesia depending on anaesthetic concentration. The most common side effects are hypotension, tachypnoea, muscle tenseness, excitation, apnoea, muscle fasciculations and emesis.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Sevocalm and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[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