6 May 2011
EMA/CVMP/481167/2011-Corr.[1]
Committee for Medicinal Products for Veterinary Use

Summary of opinion[2]

Recuvyra

Fentanyl

On 4 May 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[3] recommending the granting of a marketing authorisation for the veterinary medicinal product Recuvyra, 50 mg/ml transdermal solution, intended for the control of post-operative pain in dogs. The applicant for this veterinary medicinal product is Procyon Pharmaceutical Ltd.

The active substance of Recuvyra is fentanyl, an opioid analgesic, which is to be applied topically with a specially designed applicator, and then absorbed through the skin.

The benefits of Recuvyra are its control of post-operative pain in dogs over an extended period of time (4 days) following single administration. The most common side effects are those typical for the class of opioids, i.e. dose-dependent sedation, mild reductions in body temperature, heart and respiratory rates, and vomiting or diarrhoea. Any skin contact with the application site should be avoided by people or other pets. For user safety reasons, dogs of more than 20 kg bodyweight should remain hospitalised for 2 days after administration of Recuvyra.

The approved indication is: Control of post-operative pain associated with major orthopaedic and soft tissue surgery in dogs.

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 to risk balance for Recuvyra and therefore recommends the granting of the marketing authorisation.

[1] Corrigendum to correct the name of the company
[2] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[3] 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union