12 December 2013
EMA/CVMP/694589/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Contacera

International non-proprietary name (INN): meloxicam

On 12 December 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted an opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Contacera. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Contacera is currently authorised as a solution for injection for cattle, pigs and horses. The extension concerns the addition of a new strength meloxicam 15 mg/ml, a new pharmaceutical form oral suspension and a new, oral route of administration for horses.

The new indication for horses is the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.

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 Contacera and therefore recommends the granting of the extension of the marketing authorisation.

[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.

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