8 October 2021
EMA/CVMP/544339/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Zenalpha

International non-proprietary name (INN): medetomidine hydrochloride / vatinoxan hydrochloride

On 7 October 2021, 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 Zenalpha, solution for injection, intended for dogs. The applicant for this veterinary medicinal product is Vetcare Oy. The applicant is registered as a micro, small and medium-sized enterprise (SME) pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Zenalpha is a sedative and analgesic product containing medetomidine hydrochloride/vatinoxan hydrochloride (ATCvet code QN05CM99) as active substance. Medetomidine hydrochloride is a potent α_2-adrenoreceptor agonist authorised as a sedative, and vatinoxan hydrochloride, a selective α_2-adrenoreceptor antagonist. In combination, the two active substances are proposed to prevent or attenuate the adverse cardiovascular effects of medetomidine.

The benefit of Zenalpha is its efficacy in the provision of sedation and analgesia during the conduct of non-invasive, non-painful or mildly painful procedures and examinations up to 30 minutes. The most common side effects are hypothermia, bradycardia and tachycardia.

The full indication is: To provide restraint, sedation and analgesia during conduct of non-invasive, non-painful or mildly painful procedures and examinations intended to last no more than 30 minutes.

Detailed conditions for the use of this product are 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 Zenalpha 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union