8 November 2019
EMA/CVMP/560649/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Stelfonta

International non-proprietary name (INN): tigilanol tiglate

On 7 November 2019, 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 Stelfonta, solution for injection, intended for dogs. The applicant for this veterinary medicinal product is QBiotics Netherlands B.V. The applicant is registered as a SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Stelfonta is an antineoplastic medicinal product containing tigilanol tiglate (ATCvet code QL01XX91) as active substance, which activates the protein kinase C (PKC) signalling cascade, and the induction of necrosis in cells that are in direct contact with tigilanol tiglate.

The benefits of Stelfonta are its effectiveness in the treatment of non-resectable, non-metastatic (WHO staging) subcutaneous mast cell tumours, which are located at or distal to the elbow or the hock, and non-resectable, non-metastatic cutaneous mast cell tumours in dogs. The most common side effects in treated dogs are pain upon injection, and wound formation at the injection site associated with pain and lameness; as well as vomiting and tachycardia.

The appropriate CVMP guidelines on data requirements for veterinary medicinal products intended for minor use or minor species/limited markets have been applied in the assessment of the application.

The full indication is: for the treatment of non-resectable, non-metastatic (WHO staging) subcutaneous mast cell tumours located at or distal to the elbow or the hock, and non-resectable, non-metastatic cutaneous mast cell tumours in dogs. Tumours must be less than or equal to 8 cm^3 in volume, and must be accessible to intratumoral injection.

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.

[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

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