EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicine and Product Data Management

Committee for Medicinal Products for Veterinary Use

Summary of opinion*

BTVPUR AlSap 2-4

Inactivated vaccine against bluetongue virus serotypes 2 and 4

On 14 July 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation under exceptional circumstances for the veterinary medicinal product BTVPUR AlSap 2-4, suspension for injection, intended for the active immunisation of sheep to prevent viraemia and to reduce clinical signs caused by bluetongue virus serotypes 2 and 4. The applicant for this veterinary medicinal product is Merial S.A.S.

The active substance of BTVPUR AlSap 2-4 is the inactivated blutongue virus, serotype 2 and incativated bluetongue virus serotype 4.

The benefits of BTVPUR AlSap 2-4 are the stimulation of active immunity in sheep resulting in the prevention of viraemia and reduction of clinical signs caused by bluetongue serotypes 2 and 4.

The CVMP considered that due to the current epidemiological situation of bluetongue and the consequent threat to animal health there are objective and verifiable reasons for recommending the granting of a Marketing Authorisation under exceptional circumstances for this product, namely that

- the remaining epidemiological risk for European sheep populations constitutes an objective need to have authorised products available for use in the coming months.
- the application has met the requirements of the CVMP guideline on Minimum Data Requirements for an Authorisation Under Exceptional Circumstances for Vaccines for Emergency Use Against Bluetongue (EMEA/CVMP/ IWP/ 220193/2008).
- the applicant has agreed to the necessary post-authorisation commitments and specific obligations, to assure the safe use of the product in the field.

The applicant cannot reasonably be expected to provide the results from certain trials on the target species for duly substantiated reasons.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.
** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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The most common side effects are a small local swelling at the injection site (at most 24 cm^2) for a short period (at most 14 days) and a transient increase in body temperature, normally not exceeding an average of 1.1°C, may occur within 24 hours after vaccination.

The approved indication is:

"*Active immunisation of sheep to prevent viraemia* and to reduce clinical signs caused by bluetongue virus serotypes 2 and 4.*

**(below the level of detection by the validated RT-PCR method at 3.68 log10 RNA copies/ml, indicating no infectious virus transmission)*

Onset of immunity has been demonstrated 3 and 5 weeks after the primary vaccination course for serotype 4 and serotype 2, respectively.

The duration of immunity is not yet established".

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 BTVPUR AlSap 2-4 and therefore recommends the granting of the marketing authorisation under exceptional circumstances.[***]

[***] Marketing Authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.