European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
ZULVAC 8 OVIS

INACTIVATED BLUETONGUE VIRUS, SEROTYPE 8

On 11 November 2009, 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 Zulvac 8 Ovis, suspension for injection, intended for the active immunisation of sheep from 1.5 months of age for the prevention of viraemia caused by Bluetongue Virus, serotype 8. The Applicant for this veterinary medicinal product is Fort Dodge Animal Health.

The active substance of Zulvac 8 Ovis is the inactivated Bluetongue Virus (BTV) Serotype 8.

The benefit of Zulvac 8 Ovis is the stimulation of active immunity in sheep against bluetongue virus, serotype 8.

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 and cattle populations constitutes an urgent and objective need to have authorised products available for use in the coming months.
- the application has met the requirements of the CVMP Guideline on the 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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu
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The most common side effect is potentially a transient increase in rectal temperature, not exceeding 1.2°C, that may occur during the 24 hours following vaccination. Vaccination may be followed in most animals by a local reaction at the injection site. These reactions take the form in most cases of a general swelling of the injection site (persisting for not more than 7 days) or of palpable nodules (subcutaneous granuloma, possibly persisting for more than 48 days).

The approved indication is: ''Active immunisation of sheep from 1.5 months of age for the prevention* of viraemia caused by Bluetongue Virus, serotype 8''.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

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 Zulvac 8 Ovis 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.