EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 March 2014
EMA/CVMP/109591/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

AFTOVAXPUR DOE

Common name:

Purified, inactivated foot-and-mouth disease virus strain A Turkey 14/98 /
Purified, inactivated foot-and-mouth disease virus strain A22 Iraq /
Purified, inactivated foot-and-mouth disease virus strain A24 Cruzeiro /
Purified, inactivated foot-and-mouth disease virus strain Asia1 Shamir /
Purified, inactivated foot-and-mouth disease virus strain O Taiwan 3/97 /
Purified, inactivated foot-and-mouth disease virus strain O1 BFS /
Purified, inactivated foot-and-mouth disease virus strain O1 Manisa /
Purified, inactivated foot-and-mouth disease virus strain SAT2 Saudi Arabia

On 13 March 2014, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product AFTOVAXPUR DOE. The marketing authorisation holder for this veterinary medicinal product is MERIAL.

AFTOVAXPUR DOE consists of up to three types of inactivated, purified foot-and-mouth disease virus antigens, chosen from seven that are included in the dossier, in a double oil emulsion adjuvant.

The change agreed by the CVMP concerns the addition of a new foot-and-mouth disease virus antigen strain: SAT2 Saudi Arabia to take into account recommendations of the World Reference Laboratory for FMD for antigens to be included in banks. This addition of the SAT2 Saudi Arabia strain to the list of strains increases the strains which may be included in the vaccine either alone or in combination with up to two of the other listed strains.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SPC) which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[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.

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