9 November 2018
EMA/CVMP/722013/2018
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 8 November 2018, 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 is currently authorised as emulsion for injection for the active immunisation of cattle, sheep and pigs against foot-and-mouth disease to reduce clinical signs. The variation concerns the change of the onset of immunity in cattle and sheep.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2018. Reproduction is authorised provided the source is acknowledged.