Prequalification of foot-and-mouth disease vaccine

Product Overview:

Tradename: FMDVAX Oil Emulsion Vaccine

Manufacturer: FMDVAC Pty Limited, Armidale, Australia

WWW: www.fmdvac.com

Image:

National Regulatory Authority (NRA) where product is registered/authorized:

APVMA, Australia Reg No: 91351/131935 Date registered 2022-12-09 https://apvma.gov.au/

ANMV, France Reg No: 91351/131935 Date registered 12/03/2005 www.anmv.fr

VMD United Kingdom Reg No: 91351/131935 Date registered 04/05/1999 www.vmd.uk

The Summary of Product Characteristics (SPC), vaccine label and product information/package insert may be found via the hyperlinks to the respective NRA.

Prequalification

Prequalification number: PQv22-001

Prequalification date: 01/05/2023

Prequalification status Current

Product Description

Target Species: **Cattle, pigs, sheep & goats**

Active ingredients

Up to 3 vaccine strains per vaccine formulation. The number and type of strains included in the final product will be adapted to the current epidemiological situation at the time of formulation of the final product and will be shown on the label.

Active ingredients*	Potency
Asia 1 Shamir	≥ 6PD50*
O1 Manisa	≥ 6PD50
A24 Cruzeiro	≥ 6PD50
SAT2 Saudi Arabia	≥ 6PD50
SAT1 3571	≥ 6PD50

*PD50 – 50% protective dose in cattle as described in the WOAH Terrestrial Manual

Adjuvant: Liquid paraffin (oil emulsion)

Shelf life: 24 months

Presentations: polypropylene

20ml (10 cattle/pig doses, 20 sheep/goat doses)

50ml (25 cattle/pig doses, 50 sheep/goat doses)

100ml, (50 cattle/pig doses, 100 sheep/goat doses)

250ml (125 cattle/pig doses/ 250 sheep/goat)

Storage & transport: 2-8 °C

Indications: Reduction in clinical signs of foot-and-mouth disease.

Onset of immunity: 7 days after primary vaccination schedule for all species.

Duration of immunity: 6 months for all species as measured by neutralizing antibodies above those shown to be protective in challenge studies.

DIVA: The Inactivated foot-and-mouth disease antigens in FMDVAX are purified and do not contain sufficient amounts of non-structural proteins (NSP) to induce an antibody response following administration of a trivalent vaccine containing an amount of antigen corresponding to ≥ 6PD50. NSPs were no detected by three commercial kits after three vaccinations.

Primary Vaccination schedule: 2 doses 2-4 weeks apart from 4 weeks of age in all species
Revaccination: a booster dose should be given every six months to maintain protective immunity.
Storage & transport: 2-8°C