



PREQUALIFICATION OF FOOT-AND-MOUTH DISEASE VACCINE

Product overview

Tradename	AFTOPOR
Manufacturer	Boehringer Ingelheim Animal Health
WWW	https://www.boehringer-ingelheim.com

Product image for the Aftopor bottle





Country/region, National Regulatory Authority (NRA) or regional authority where product is registered/authorized and authorization reference:

AUSTRALIA	
FRANCE	<i>FR/V/6308186 0/2017</i>
GERMANY	
HONG-KONG	
INDONESIA	
IRAN	
ISRAEL	
LEBANON	
MALAYSIA	
NEW ZEALAND	
SOUTH KOREA	
TAIWAN	
THAILAND	
UNITED KINGDOM	
UNITED STATES OF AMERICA	
VIETNAM	



Prequalification

Prequalification number:	PQv22-006
Prequalification date:	21 Nov 2023
Prequalification status:	Current

Product description

Target species	Cattle, sheep, pigs
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Active ingredients:

Active ingredient	Potency per dose
Between one and eight inactivated and purified Foot-and-Mouth Disease strains (serotypes O, A, Asia1, SAT) O1 Manisa O Panasia-2 O BFS O1 Campos A22-Iraq A24 Cruzeiro A GVII-2015 A Iran-05 A Malaysia-12 A Malaysia-97 A Saudi-95 A Eritrea 98 Asia1 Shamir SAT1 Rho SAT2 Eri SAT2 Zim	≥6 PD ₅₀ * per strain

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



Adjuvant	Mineral oil
Formulation	Water-in-oil-in-water emulsion
Shelf life	18 months
Shelf life after first opening	Use immediately after first opening.
Storage and transport	2°C – 8°C Protect from light. Do not freeze.
Presentations	Polypropylene bottle 20 ml, 50 ml, 100 ml, 200 ml, 300 ml
Indications	Active immunization to reduce clinical signs and mortality following exposure to foot-and-mouth disease virus.
Onset of immunity	10 days after the first injection of primary vaccination
Duration of immunity	6 months after the completion of the primary vaccination in cattle and sheep and 4 months in pigs.

DIVA (Differentiate Infected from Vaccinated Animals):

AFTOPOR has potential marker properties for use in DIVA (Differentiating Infected from Vaccinated Animals): repeated administration of AFTOPOR vaccine does not induce antibodies against the viral Non-Structural (NSP) using the OIE enzyme-linked immunoelectro-transfer blot analysis test for antibodies against Non-Structural Proteins (Manual of Standards for Diagnostic Tests and Vaccines Foot and Mouth Disease, Paris)

Primary vaccination schedule:

Pigs:

Naïve animals: one injection starting at 2 weeks of age and followed by a second vaccination 4 weeks later.

Animals with maternally-derived antibodies: one injection starting at 8 weeks of age and followed by a second vaccination 4 weeks later.



Cattle, sheep:

Naïve animals: One injection starting at 2 weeks of age and followed by a second vaccination 4 weeks later.

Animals with maternal-derived antibodies: One injection starting at 12 weeks of age followed by a second vaccination 4 weeks later.

Revaccination:

- Pigs: One injection every 4 months.
 - Cattle and sheep: One injection every 6 months.
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