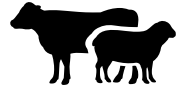


HEXA-APHTHOVAC™

TRANSBOUNDARY
CONTROL



Inactivated emulsified hexavalent vaccine for immunization of cloven-hoofed animals against Foot and Mouth Disease

INTRODUCTION

Foot-and-mouth disease (FMD) is a highly contagious viral disease of cloven-hoofed animals. The disease was initially described in the 16th century and was the first animal pathogen identified as a virus. The transboundary spread and significant economic impact have increased the concern of national authorities worldwide to deploy integrated control measures under the frame of National Control Programs.¹

The causal agent is the foot-and-mouth disease virus (FMDV) which belongs to the Aphthovirus genus of the *Picornaviridae* family. Seven serotypes (A, O, C, Asia 1, and South African Territories 1, 2, and 3) have been identified serologically, and multiple subtypes occur within each serotype.¹

Traditional FMD vaccines contain defined amounts of one or more chemically inactivated preparations of a seed virus strain blended with a suitable adjuvant and excipients. According to WOAHP, commercial FMD vaccines should comply with important criteria: i) formulated with sufficient antigen and appropriate adjuvant to have a minimum potency level of 3 PD₅₀ [50% protective dose]; ii) provide 6 months of immunity after two initial vaccinations given 1-month apart; iii) vaccine strains are selected based on antigenic relationship with circulating strains.²

COMPOSITION (before inactivation)

- FMD A-Iran-05 strain ≥ 6.0 PD₅₀/dose.
- FMD A-Africa-GIV strain ≥ 6.0 PD₅₀/dose.
- FMD Asia 1/Shamir strain ≥ 6.0 PD₅₀/dose.
- FMD O-PanAsia2 strain ≥ 6.0 PD₅₀/dose.
- FMD O-EA-3 strain ≥ 6.0 PD₅₀/dose.
- FMD O-Manisa-69 strain ≥ 6.0 PD₅₀/dose.

VACCINE ADJUVANT

Oil adjuvant.

TARGET SPECIES

Cattle, buffalo, sheep, goat and pigs.

INDICATIONS

For immunization of cloven-hoofed animals against Foot and Mouth Disease (FMD).

IMMUNITY

- Onset of immunity takes place after 3 weeks.
- Duration of immunity is at least 6 months.

VACCINATION PROGRAM

Animals can be vaccinated from early age, as per advice from your veterinarian.

- Animals from vaccinated parents: from 3 months of age.
- Animals from unvaccinated parents: from 1 month of age.
- Booster dose shall be administered 4 weeks after the primary vaccination and then biannually.

WITHDRAWAL

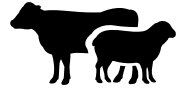
Zero days for meat and milk.

CONSIDERATIONS

Some animals may develop swelling at the site of injection. These swellings will disappear within three days.

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DOSAGE

- **Cattle and buffalo:** 3 mL per animal via subcutaneous injection.
- **Sheep and goat:** 1 mL per animals via subcutaneous injection.
- **Pigs:** 3 mL per animal via intramuscular injection.

ADMINISTRATION

- Shake well before use.
- Allow the vaccine to reach room temperature (+20 to +25°C) before use.
- Use sterile injection equipment.
- Use the entire contents when first opened.
- The vaccine may occasionally separate into two layers on storage. This in no way affects its potency, but the vaccine should be shaken vigorously before and during use to ensure good emulsification.
- Do not use HEXA-APHTHOVAC™ if you notice critical irreversible separation of the emulsion.
- Shelf life: 24 months after manufacturing date.
- Shelf life after first opening the container: 3 hours.

PRESENTATION

HEXA-APHTHOVAC™ is packed and presented in polyethylene terephthalate (PET) bottles of 50 mL, 100 mL and 300 mL, containing respectively 15, 30 and 100 doses.

References

1. Grubman and Baxt (2004). Foot-and-Mouth Disease. *Clin Microbiol Rev.* 2004 Apr; 17(2): 465-493. doi: 10.1128/CMR.17.2.465-493.2004
2. WOAHP (2021). *Technical Disease Cards.* OIE Science Department. Last updated January 2021.

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