SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOPUR DOE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Purified inactivated Foot and Mouth disease virus antigen
Between one and four strains per dose
Between a minimum of 3 and a maximum of 15µg 146S antigen per strain to ensure a potency of at least $3PD_{50}$ in cattle

Adjuvant(s):
Double oil emulsion containing light paraffin oil, sorbitan mono-oleate and mannide mono-oleate as components of the oil emulsion 360.15mg

Excipient(s):
Chloroform, at most 10 mg/ml.

For a full list of excipients, see section 6.1**.**

3. PHARMACEUTICAL FORM

Homogenous cream opaque double oil emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs and ruminants.

4.2 Indications for use, specifying the target species

For the active immunisation of ruminants and pigs to reduce clinical signs and mortality following exposure to Foot-and-Mouth Disease virus.

The onset of immunity is 3 weeks (demonstrated by challenge). Immunity lasts 6 months in cattle and at least 4 weeks in pigs (see section 4.9 for recommended vaccination program).

4.3 Contraindications

Do not use in unhealthy animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

None.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

If the vaccine is accidentally injected into man, urgent medical attention is necessary.

To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the doctor:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

Vaccination in both cattle and pigs may be followed by a small local swelling usually up to 0.5cm diameter at the site of injection and the detection of granulomas at the site of injection at post mortem. Transient pyrexia may also be seen. The maximum size of injection site reaction noted in an overdose safety study in cattle was 11.5cmx7.2cmx1.2cm. Histological examination of injection site reactions after administration of a single dose or an overdose revealed sterile granulomas. The duration of the histological lesions was not studied but they are likely to persist for several months. Injection site sterile granulomas are seen in up to 50% of animals following the second or subsequent administration of vaccine and these last for up to 14 days.

4.7 Use during pregnancy, lactation or lay

This has not been studied under controlled laboratory conditions, but experience in the field suggests that vaccination of pregnant animals is safe.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. However, experience in the field suggests that the vaccine may be used satisfactorily with a range of bacterial and viral vaccines. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Dosages: Large ruminants 2ml; Small ruminants 1ml; Pigs 2ml.

Shake before use.
The vaccine is to be administered by the Intramuscular Route. The preferred site in pigs is the neck, behind the ear, and, in ruminants, the area of the shoulder.

Primary Course of Vaccination for Pigs:
One injection starting at 8 weeks of age and followed by a second vaccination 4 weeks later.

Boosters for Pigs
Where there is a likelihood of challenge with Foot and Mouth Disease Virus pigs should be vaccinated every four weeks to maintain epidemiologically-relevant immunity.

Primary Course of Vaccination for Ruminants:
One injection starting at 2 weeks of age followed by a second vaccination 4 weeks later.

Boosters for Ruminants:

Animals should be administered a booster vaccination every 6 months.

No studies have been carried out in animals with maternally-derived immunity. The vaccine can be administered to seronegative pigs from 8 weeks of age and to seronegative calves from 2 weeks of age.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Macroscopic and histological examination of injection site reactions after administration of a single dose and an overdose reveal sterile granulomas. The duration of the histological lesions was not studied but they are likely to persist for several months.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunological Inactivated virus vaccines
ATCvet code: **QI02AA04**

Inactivated Foot and Mouth Disease vaccine containing one or several appropriate serotypes of Types O, A, C, Asia 1, SAT 1, SAT 2, SAT 3 in a double oil emulsion adjuvant. The strains and antigen content of the vaccine are formulated to provide epidemiologically-relevant immunity in vaccinated animals. Vaccination of animals induces the production of antibodies that reduce clinical signs and mortality following exposure to Foot and Mouth Disease virus.

Repeated administration to cattle under experimental conditions on 3 consecutive occasions over a period of two months of maximum payload AFTOPUR DOE foot and mouth disease vaccine containing 16µg of 146S antigen of each of four strains per dose has been demonstrated not to induce titres of antibodies against the Non-Structural proteins of the virus sufficient to result in the serum scoring positive in the enzyme-linked immunoelectro-transfer blot analysis test for antibodies against Non-Structural proteins (Manual of Standards for Diagnostic Tests and Vaccines [2001] Foot and Mouth Disease, Chapter 2.1.1. Office International des Epizooties, Paris) in contrast to animals infected with foot and mouth disease virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light paraffin oil,
Sorbitan mono-oleate
Mannide mono-oleate
Ester of fatty acids and of ethoxylated polyols
Chloroform
Sodium chloride
Potassium chloride
Magnesium chloride
Monosodium phosphate
Glucose
Calcium chloride
Sodium bicarbonate

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product**.**

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months.

6.4 Special precautions for storage

Store and transport vaccine at 2-8^{o}C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Polypropylene bottle 20 ml, 50 ml, 100ml, 200 ml, 300 ml
Nitrile rubber stoppers and crimp fitting aluminium collars with a removable centre piece (tamper evident).
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/3001

9. DATE OF FIRST AUTHORISATION

21 December 2000

10. DATE OF REVISION OF THE TEXT

July 2021

PROHIBITION OF SALE, SUPPLY AND/OR USE

The manufacture, import, possession, sale, supply and/or use of AFTOPUR DOE may be prohibited in a Member States on the whole or part of its territory pursuant to

national legislation. Any person intending to manufacture, import, possess, sell, supply and/or use AFTOPUR DOE must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

Approved 29 July 2021