PACKAGE LEAFLET

AFTOPUR DOE

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
[To be completed nationally]

Manufacturer responsible for the batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 SAINT PRIEST
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOPUR DOE

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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.

Double oil emulsion for injection

4. INDICATION(S)

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).

5. CONTRAINDICATIONS

Do not use in unhealthy animals.

6. ADVERSE REACTIONS

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. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs and ruminants

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

. Apply usual procedures for the handling of the animals.
. Vaccinate only healthy animals.
. Shake before use.
. Apply usual aseptic procedures.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport vaccine at 2°C - 8°C.
Do not freeze.
Protect from light.

12. SPECIAL WARNING(S)

Use during pregnancy, lactation or lay has not been studied under controlled laboratory conditions, but experience in the field suggests that vaccination of pregnant animals is safe.

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.

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.

Do not mix with any other vaccine or immunological product.

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.

The manufacture, import, possession, sale, supply and/or use of AFTOPUR DOE may be prohibited in a Member State 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

[To be completed nationally]

15. OTHER INFORMATION

To be used only on veterinary prescription.

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.

Polypropylene bottle 20 ml, 50 ml, 100 ml, 200 ml, 300 ml

Not all pack sizes may be marketed.