MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Polypropylene bottle of 20-ml
Polypropylene bottle of 50-ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOPUR AlSap

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Purified inactivated Foot and Mouth disease virus antigen
Virus strain (s): xxxx
Up to 15μg 146S antigen per strain to ensure a potency of at least 3 PD_{50}.

3. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBERS OF DOSES

20-ml polypropylene bottle
50-ml polypropylene bottle

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous route.
Dose: Large ruminants 2ml
Small ruminants 1ml

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY

For animal treatment only

Keep out of reach of children
Store at 2-8^{0}C. Do not freeze. Protect from light. Shake before use.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Polypropylene bottle of 100-ml
Polypropylene bottle of 200-ml
Polypropylene bottle of 300-ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOPUR AlSap

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Purified inactivated Foot and Mouth disease virus antigen
Virus strain(s): xxxx
Up to 15μg 146S antigen per strain to ensure a potency of at least 3 PD_{50}.

Adjuvant(s):

Aluminium hydroxide	5.0 - 7.5 mg
Purified Saponin	90 HU

Excipient(s):
Chloroform, at most 6 mg/ml

3. PHARMACEUTICAL FORM

Aqueous suspension for injection

4. PACKAGE SIZE

1 polypropylene bottle of 100 ml
1 polypropylene bottle of 200 ml
1 polypropylene bottle of 300 ml

5. TARGET SPECIES

Ruminants

6. INDICATION(S)

For the active immunisation of ruminants to reduce clinical signs and mortality associated with Foot-and-Mouth Disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous route.
Read the package leaflet before use
Dose: Large ruminants 2ml
Small ruminants 1ml

8. WITHDRAWAL PERIOD

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Shake before use

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

[Not requested on the immediate label]

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/5002

17. MANUFACTURER'S BATCH NUMBER

Batch:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

AFTOPUR AlSap

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

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer for the batch release:
Boehringer Ingelheim Animal Health UK Ltd, Biological Laboratory, Ash Road, Pirbright, Surrey GU24 0NQ
United Kingdom

Or

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 AlSap

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
Up to 15μg 146S antigen per strain to ensure a potency of at least 3 PD_{50}.

Adjuvant(s):

Aluminium hydroxide	5.0 - 7.5 mg
Purified Saponin	90 HU

Excipient(s):
Chloroform, at most 6 mg/ml

Aqueous suspension for injection.

4. INDICATION(S)

For the active immunisation of ruminants to reduce clinical signs and mortality associated with Foot-and-Mouth Disease.
The onset of immunity is 3 weeks (demonstrated by challenge). Immunity lasts 6 months.

5. CONTRAINDICATIONS

Do not use in unhealthy animals

6. ADVERSE REACTIONS

Vaccination may be followed by a small local swelling and/or slight pyrexia of short duration. The maximum local swelling occurs 48 hours after vaccination and covers at an extreme an average area of 24 cm^2. In nearly all animals the local swelling had disappeared within one month after vaccination.

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

7. TARGET SPECIES

Ruminants

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

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

Shake before use.
The vaccine is to be administered by the Subcutaneous Route. The preferred site is in the area of the shoulder.

Primary Vaccination:
Two injections, 3 to 4 weeks apart, starting at 2 weeks of age for young animals from unvaccinated dams or 2.5 months of age for young animals from vaccinated dams. In the event of an epidemic, the first injection should be given to all animals as early as 2 weeks of age.

Boosters:
Normally, boosters should be given every 6 months, depending on the epidemiological situation and in accordance with local legislation.

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.

At overdose there may be a mild localised inflammatory effect or swelling at the injection site, typically of up to 6cm diameter and of less than one month duration.

Do not mix with any other vaccine or immunological product.

The manufacture, import, possession, sale, supply and/or use of AFTOPUR AlSap 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 AlSap 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

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 an aluminium hydroxide/saponin. The strains and antigen content of the vaccine are formulated to provide epidemiologically-relevant immunity in vaccinated animals. Vaccination of ruminants induces the production of antibodies to Foot-and-Mouth Disease virus that reduce clinical signs and mortality following exposure to the agent. Repeated administration to cattle under experimental conditions on 5 consecutive occasions over a period of four months of maximum payload AFTOPUR ALSAP 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, 100ml, 200 ml, 300 ml

Not all pack sizes may be marketed.

Approved 13 August 2021