SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOPUR AlSap

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Homogenous milky white aqueous suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Ruminants.

4.2 Indications for use, specifying the target species

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 (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

None.

4.6 Adverse reactions (frequency and seriousness)

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.

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.

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.

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

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.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: **Foot and mouth disease Inactivated virus vaccine for Ruminants** - for cattle
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 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Purified saponin
Glycine buffer
Silicone antifoam emulsion
Phosphate Buffer Solution
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°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 Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

08327/3002

9. DATE OF FIRST AUTHORISATION

07 June 2000

10. DATE OF REVISION OF THE TEXT

January 2019

PROHIBITION OF SALE, SUPPLY AND/OR USE

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

Approved: 08 January 2019

D Austin