ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

Medicinal product no longer authorised

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOVAXPUR DOE emulsion for injection for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml of emulsion contains:

Active substances:
Maximum three of the following purified, inactivated foot-and-mouth disease virus strains:
O1 Manisa .....≥ 6 PD_{50}*
O1 BFS .....≥ 6 PD_{50}*
O Taiwan 3/97 ..... ≥ 6 PD_{50}*
A22 Iraq..... ≥ 6 PD_{50}*
A24 Cruzeiro ..... ≥ 6 PD_{50}*
A Turkey 14/98 ..... ≥ 6 PD_{50}*
Asia 1 Shamir .....≥ 6 PD_{50}*
SAT2 Saudi Arabia ..... ≥ 6 PD_{50}*

* PD_{50} – 50% protective dose in cattle as described in Ph. Eur. monograph 0063.

The number and type of strains included in the final product will be adapted to the current epidemiological situation at the time of formulation of the final product and will be shown on the label.

Adjuvant:
Liquid paraffin .....537 mg.

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White emulsion after shaking.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

Active immunisation of cattle, sheep and pigs from 2 weeks of age against foot-and-mouth disease to reduce clinical signs.

Onset of immunity:
Cattle and sheep: 7 days after vaccination.
Pigs: 4 weeks after vaccination.

Medicinal product no longer authorised

Duration of immunity: vaccination of cattle, sheep and pigs induced the production of neutralising antibodies that persisted for at least 6 months. In cattle, the antibody levels measured were above those shown to be protective.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
Maternal antibodies may interfere with vaccination. Schedule should be adjusted accordingly (see section 4.9).
When very young pigs (at 2 weeks old) have to be vaccinated, revaccination at 8-10 weeks is recommended

4.5 Special precautions for use

Special precautions for use in animals

None.

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

To the user:
This veterinary medicinal 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 physician:
This veterinary medicinal 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)

Swellings (diameter of up to 12 cm in ruminants and 4 cm in pigs) occurred very commonly in most animals after administration of a dose of vaccine. These local reactions normally resolve over a period of four weeks post vaccination, but may persist for longer in a small number of animals.
A slight increase of rectal temperature of up to 1.2 °C for 4 days post-vaccination with no other generalised clinical signs is commonly observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Medicinal product no longer authorised

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

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. 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

Homogenize the content of the vial by gentle mixing before the insertion of needle. This is best achieved by inverting the vial several times base over apex. Do not mix the vaccine by vigorous shaking because it leads to entrapment of air bubbles.
Do not warm the product before use.
Apply usual aseptic procedures. Avoid accidental contamination of the vaccine after first broaching and during use.

Primary vaccination:
Cattle from 2 weeks of age: one dose of 2 ml, by subcutaneous route.
Sheep from 2 weeks of age: one dose of 2 ml, by subcutaneous route.
Pigs from 2 weeks of age: one dose of 2 ml, by intramuscular route.
The use of a multiple injection device is recommended.

Revaccination: every six months.

When animals have to be vaccinated in presence of maternal antibodies, revaccination at 8-10 weeks is recommended.

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

No adverse reactions except those mentioned in section 4.6 were observed after the administration of a double dose to calves, lambs and piglets.
In some cases ulceration may occur at the injection site. Following repeated administration at short intervals, the intensity of these reactions may be increased.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmaceutical group: inactivated viral vaccine, foot-and-mouth disease virus.
ATCvet code: QI02AA04.

To stimulate active immunity of cattle, sheep and pigs against purified, inactivated foot-and-mouth disease virus strain antigens related to those contained in the vaccine.

Medicinal product no longer authorised

In trials the following has been demonstrated:
Vaccination of cattle with strains O1 Manisa, O1 BFS, A22 Iraq, A24 Cruzeiro, A Turkey 14/98, Asia1 Shamir and SAT2 Saudi Arabia resulted in a reduction of clinical signs in animals exposed to infection.
Vaccination of sheep with strain O1 Manisa resulted in a reduction of clinical signs in animals exposed to infection.
Vaccination of pigs with strain Asia1 Shamir resulted in a reduction of clinical signs and virus shedding in animals exposed to infection. Vaccination of pigs with strains O Taiwan 3/97 and A22 Iraq resulted in a reduction of clinical signs in animals exposed to infection.

Inactivated foot-and-mouth disease antigens are purified and do not contain sufficient amounts of non-structural proteins (NSP) to induce an antibody response following administration of a trivalent vaccine containing an amount of antigen corresponding with at least 15 PD_{50} per strain per dose of 2 ml.

No antibodies to NSP were detected using the PrioCHECK FMDV NS test kit:

- in cattle following administration of a double dose followed by a single dose 7 weeks later and a third vaccination with a single dose 13 weeks after the second dose,
- in sheep following administration of a double dose followed by a single dose 5 weeks later and a third vaccination with a single dose 7 weeks after the second dose,
- in pigs following administration of a double dose followed by a single dose 3 weeks later and a third vaccination with a single dose 7 weeks after the second dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, liquid
Mannide mono-oleate
Polysorbate 80
Trometamol
Sodium chloride
Potassium dihydrogen phosphate
Potassium chloride
Disodium phosphate anhydrous
Potassium hydroxide
Water for injections.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product not containing strain Asia1 Shamir as packaged for sale: 6 months.
Shelf life of the veterinary medicinal product containing strain Asia1 Shamir as packaged for sale: 2 months.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.

Medicinal product no longer authorised

Protect from light.

6.5 Nature and composition of immediate packaging

Polypropylene bottle with a nitrile elastomer closure and sealed with an aluminium cap.

Pack sizes:
- Cardboard box with 1 bottle of 10, 25, 50, 100 or 150 doses;
- Cardboard box with 10 bottles of 10, 25, 50, 100 or 150 doses.

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 product should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/153/001– 850

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15/07/2013
Date of last renewal: 14/06/2018

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.
The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of foot-and-mouth disease.

Medicinal product no longer authorised

Medicinal product no longer authorised

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLS

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substances

BOEHRINGER INGELHEIM ANIMAL HEALTH Netherlands B.V.
Houtribweg 39
8221 RA Lelystad
The NETHERLANDS

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'aviation
69800 Saint Priest
FRANCE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of foot-and-mouth disease.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

Medicinal product no longer authorised

ANNEX III

LABELLING AND PACKAGE LEAFLET

Medicinal product no longer authorised

A. LABELLING

Medicinal product no longer authorised

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOVAXPUR DOE emulsion for injection for cattle, sheep and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated FMD antigen, ≥ 6 cattle PD_{50} per strain.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

10 doses
25 doses
50 doses
100 doses
150 doses
10 x 10 doses
10 x 25 doses
10 x 50 doses
10 x 100 doses
10 x 150 doses

5. TARGET SPECIES

Cattle, sheep and pigs

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle and sheep: for subcutaneous use.
Pigs: for intramuscular use.

Read the package leaflet before use.

Medicinal product no longer authorised

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

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

Disposal: read package leaflet.

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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Medicinal product no longer authorised

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/153/001-850

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Medicinal product no longer authorised

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 50, 100 and 150 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOVAXPUR DOE
Emulsion for injection for cattle, sheep and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated FMD antigen, ≥ 6 cattle PD_{50} per strain.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

50 doses
100 doses
150 doses

5. TARGET SPECIES

Cattle, sheep, and pigs

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle and sheep: SC.
Pigs: IM.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

Medicinal product no longer authorised

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

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 SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/153/001-850

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Medicinal product no longer authorised

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 10 or 25 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOVAXPUR DOE
Emulsion for injection for cattle, sheep and pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

FMD antigen ≥ 6 PD_{50} per strain

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 doses
25 doses

4. ROUTES OF ADMINISTRATION

Cattle, sheep: SC.
Pigs: IM.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Medicinal product no longer authorised

B. PACKAGE LEAFLET

Medicinal product no longer authorised

PACKAGE LEAFLET:
AFTOVAXPUR DOE emulsion for injection for cattle, sheep and pigs

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 Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for 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

AFTOVAXPUR DOE emulsion for injection for cattle, sheep and pigs

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

Each dose of 2 ml of emulsion contains:

Active substances:
Purified, inactivated foot-and-mouth disease virus strain antigens, at least 6 PD_{50}* per strain.
* PD_{50} – 50% protective dose in cattle as described in Ph. Eur. monograph 0063.

The number and type of strains included in the final product will be adapted to the current epidemiological situation at the time of formulation of the final product and will be shown on the label.

Adjuvant:
Liquid paraffin 537 mg.

White emulsion after shaking.

4. INDICATIONS

Active immunisation of cattle, sheep and pigs from 2 weeks of age against foot-and-mouth disease to reduce clinical signs.

Onset of immunity:
Cattle and sheep: 7 days after vaccination.
Pigs: 4 weeks after vaccination.

Medicinal product no longer authorised

Duration of immunity: vaccination of cattle, sheep and pigs induced the production of neutralising antibodies that persisted for at least 6 months. In cattle, the antibody levels measured were above those shown to be protective.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Swellings (diameter of up to 12 cm in ruminants and 4 cm in pigs) occurred very commonly in most animals after administration of a dose of vaccine. These local reactions normally resolve over a period of four weeks post vaccination, but may persist for longer in a small number of animals.
A slight increase of rectal temperature of up to 1.2 °C for 4 days post-vaccination with no other generalised clinical signs is commonly observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, sheep and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Primary vaccination:
Cattle from 2 weeks of age: one dose of 2 ml, by subcutaneous route.
Sheep from 2 weeks of age: one dose of 2 ml, by subcutaneous route.
Pigs from 2 weeks of age: one dose of 2 ml, by intramuscular route.
The use of a multiple injection device is recommended.

Revaccination: every six months.

When animals have to be vaccinated in presence of maternal antibodies, revaccination at 8-10 weeks is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

Homogenize the content of the vial by gentle mixing before the insertion of needle. This is best achieved by inverting the vial several times base over apex.
Do not mix the vaccine by vigorous shaking because it leads to entrapment of air bubbles.

Do not warm the product before use.

Medicinal product no longer authorised

Apply usual aseptic procedures. Avoid accidental contamination of the vaccine after first broaching and during use.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL WARNINGS

Special warnings for each target species:
Vaccinate healthy animals only.
Maternal antibodies may interfere with vaccination. Schedule should be adjusted accordingly (see section “dosage”). .
When very young pigs (at 2 weeks old) have to be vaccinated, revaccination at 8-10 weeks is recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal 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 physician:
This veterinary medicinal 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.

Pregnancy:
Can be used during pregnancy.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Medicinal product no longer authorised

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. 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.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions except those mentioned in section "adverse reactions" were observed after the administration of a double dose to calves, lambs and piglets. In some cases ulceration may occur at the injection site. Following repeated administration at short intervals, the intensity and frequency of these reactions may be increased.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/

15. OTHER INFORMATION

To stimulate active immunity of cattle, sheep and pigs against purified, inactivated foot-and-mouth disease virus strain antigens related to those contained in the vaccine.

In trials the following has been demonstrated:
Vaccination of cattle with strains O1 Manisa, O1 BFS, A22 Iraq, A24 Cruzeiro, A Turkey 14/98, Asia1 Shamir and SAT2 Saudi Arabia resulted in a reduction of clinical signs in animals exposed to infection.
Vaccination of sheep with strain O1 Manisa resulted in a reduction of clinical signs in animals exposed to infection.
Vaccination of pigs with strain Asia1 Shamir resulted in a reduction of clinical signs and virus shedding in animals exposed to infection. Vaccination of pigs with strains O Taiwan 3/97 and A22 Iraq resulted in a reduction of clinical signs in animals exposed to infection.

Inactivated foot-and-mouth disease antigens are purified and do not contain sufficient amounts of non-structural proteins (NSP) to induce an antibody response following administration of a trivalent vaccine containing an amount of antigen corresponding with at least 15 PD_{50} per strain per dose of 2 ml.

No antibodies to NSP were detected using the PrioCHECK FMDV NS test kit:

- in cattle following administration of a double dose followed by a single dose 7 weeks later and a third vaccination with a single dose 13 weeks after the second dose,
- in sheep following administration of a double dose followed by a single dose 5 weeks later and a third vaccination with a single dose 7 weeks after the second dose,

Medicinal product no longer authorised

- in pigs following administration of a double dose followed by a single dose 3 weeks later and a third vaccination with a single dose 7 weeks after the second dose.

Pack sizes:
Cardboard box with 1 bottle of 10, 25, 50, 100 or 150 doses
Cardboard box with 10 bottles of 10, 25, 50, 100 or 150 doses

Not all pack sizes may be marketed.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of foot-and-mouth disease.

Medicinal product no longer authorised