

I. SUMMARY OF PRODUCT CHARACTERISTICS

I. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
DECIVAC FMD DOE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):

2.1

Table 1. Available Foot and mouth disease (FMD) strains:

Nr	Serotype	Subtype	Strain
1	A	5	Bernbeuren
2	A	22	Iraq
3	A	2/87	Iran
4	A	22/99	Iran
5	A	23/86	Saudi Arabia
6	A	24	Cruzeiro
7	A	81/87	Castellanos
8	A	20/06	Turkey
9	A	11/97	Malaysia
10	Asia	1	Shamir
11	C	1	Oberbayern
12	O	1	Kaufbeuren
13	O	1	Manisa
14	O	3/97	Taiwan
15	O	5/2009	Turkey
16	O	7/2010	South Korea
17	SAT	1	Zimbabwe
18	SAT	2	Zimbabwe

2.2 Monovalent

The structural viral antigen of inactivated Foot and Mouth Disease virus, i.e. one of the strains mentioned in table 1 above.

Each dose of vaccine contains at least 3 PD₅₀ of the virus type indicated.

2.3 Bivalent, trivalent and multivalent

The structural viral antigens of inactivated Foot and Mouth Disease virus, i.e. two, three or more of the strains mentioned in table 1 above. For example O1 Manisa, A Sau 23/86 and Asia1 Shamir.

Each dose of vaccine contains at least 3 PD₅₀ of each virus type indicated.

Adjuvant:

ISA Montanide 206

3. PHARMACEUTICAL FORM

Suspension for subcutaneous or intramuscular injection

I. SUMMARY OF PRODUCT CHARACTERISTICS

4. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against foot-and-mouth disease virus
ATC-vet code: QI02AA04

5. CLINICAL PARTICULARS**5.1 Target species**

Cattle, buffalo, pigs, sheep and goats

5.2 Indications for use

Active immunisation of healthy animals against serotype O, A, C, Asia1 or SAT1-2 of FMD virus as an aid in the control of FMD.

As the vaccine contains purified structural proteins, vaccination does not induce antibodies against non-structural proteins. Therefore, DECIVAC FMD DOE can be used as a marker vaccine.

5.3 Contraindications

None

5.4 Undesirable effects (frequency and seriousness)

A swelling at the site of injection may occur. In rare cases, allergic reactions may occur.

5.5 Special precautions for use

Shake well before use. Sterile injection equipment should be used.

5.6 Use during pregnancy and lactation

No information is available yet on the safety from the use of this vaccine during pregnancy or lactation.

5.7 Interaction with other medicinal products and other forms of interaction

It is recommended that no other vaccines should be administered immediately before or after vaccination with this product.

5.8 Posology and method of administration

With MDA:

Cattle, buffalo from 6 months of age 2 ml s.c. or i.m.

Pigs, from 2 months of age 2 ml i.m.

Sheep, Goats from 6 months of age 1 ml s.c. or i.m.

Basic vaccination: two injections of 1 dose each 3-5 weeks apart. Booster vaccinations are performed every 6 months.

Minimum age of vaccination of animals without maternally derived antibody against FMD: 2-3 weeks.

It is recommended to vaccinate all animals of a herd.

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

No others than described under 5.4.

5.10 Special warnings for each target species

None

I. SUMMARY OF PRODUCT CHARACTERISTICS

5.11 Withdrawal period(s)

Zero days.

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

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 insert with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

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.

6. PHARMACEUTICAL PARTICULARS**6.1 Major incompatibilities**

Do not mix with any other vaccine or immunological product.

6.2 Shelf life

1 year

6.3. Special precautions for storage

Store in a refrigerator (2°C - 8°C).

Use the content within 8 hours after opening of the bottle.

Do not freeze.

Protect from light.

6.4 Nature and contents of container

Polyethylene terephthalate (PET) plastic vials of 20, 50, 100, 250 or 500 ml with a rubber stopper and aluminum cap.

Not all pack sizes may be marketed.

6.5 Special precautions for the disposal of unused medicinal product or waste materials, 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.