MUCOSIFFA®

Product information

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MUCOSIFFA, lyophilisate and solvent for suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose of the reconstituted vaccine contains:

Active substance:

bovine viral diarrhoea attenuated live virus strain BVD-1, cytopathogenic, Oregon C24 ..... $10^{3,5}$–$10^{6,0}$ $CCID_{50}$*

* $CCID_{50}$: 50% cell culture infective dose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.
Lyophilisate: beige cake
Solvent: clear, colourless liquid.

4. CLINICAL PARTICULARS

4.1 | Target species

Cattle

4.2 | Indications for use, specifying the target species

Cattle:
• Prevention of viraemia caused by infection with bovine viral diarrhoea virus, type BVD1.
Onset of immunity: 28 days after completion of primary vaccination.
Duration of immunity: 1 year

Cows in reproduction:
• Active immunisation against transplacental infection of the foetus, with bovine viral diarrhoea virus, type BVD1.
Onset of immunity: 28 days
Duration of immunity: 1 year

4.3 | Contraindications

None

4.4 | Special warnings for each target species

In young calves, presence of maternally derived antibodies (MDA) may interfere with development of immunity following vaccination.

Vaccinate healthy animals only.

4.5 | Special precautions for use

Special precautions for use in animals

Respect usual aseptic precautions.
In contaminated environments, calves of non-vaccinated cows can be vaccinated from 8 days of age and repeated at the age of 5-6 months.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 | Adverse reactions (frequency and seriousness)

None known.

4.7 | Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

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 decided on a case by case basis.

4.9 | Amounts to be administered and administration route

For intramuscular use.

Reconstitute one dose of vaccine in 2.0 ml of solvent.
Apply sterile equipment free of antiseptics or disinfectants, for the preparation of the vaccine solution.
Withdraw 2 to 5 ml of solvent from the solvent vial and inject into the vial containing the lyophilisate. Swirl gently until the lyophilisate has dissolved. Draw up the reconstituted vaccine suspension and inject into the solvent vial. Then take 2 to 5 ml of the diluted vaccine suspension to rinse the vaccine vial and transfer it back into the solvent vial.

One dose of 2 ml is administered according to the following vaccination scheme:

Calves:
Primary vaccination:
Calves from vaccinated mothers:
First injection from 2 to 3 months of age
Second injection at 5 to 6 months of age
Revaccination: Around 1 year of age, then one injection annually.

Young calves, more than 6 months of age
Primary vaccination: One injection.
Revaccination annually.

Breeding animals, for foetal protection:
Young breeding cows: A single injection should be finalised latest 1 month prior to each mating or insemination.

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

No adverse reactions were observed after the administration of a tenfold overdose of the vaccine.

4.11 | Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for cattle, live viral vaccine against bovine viral diarrhoea (BVD)
ATC-vet code QI02AD02

The vaccine contains live, attenuated, cytopathogenic BVD-1 virus, strain Oregon C24V of bovine viral diarrhoea and aimed at prevention of viremia caused by BVD-1 virus of bovine viral diarrhoea.

In cows in reproduction, for stimulation of immunity against transplacental infection of the foetus, with bovine viral diarrhoea virus, type BVD1.

6. PHARMACEUTICAL PARTICULARS

6.1 | List of excipients

Lactose
Glutamic acid
Monopotassium phosphate
Phosphate dipotassium
Potassium hydroxide
Water for injections

6.2 | Major incompatibilities

Do not mix with any other veterinary medicinal products, except solvent supplied for use with the veterinary medicinal product.

6.3 | Shelf life and in-use shelf life

Lyophilisate:
Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after reconstitution as recommended: use the vaccine immediately
Solvent:
Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 | Special precautions for storage

Lyophilisate:
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Solvent:
Store below 25 °C.
Protect from light.

6.5 | Nature and composition of immediate packaging

Lyophilisate (freeze-dried pellet):
Type I glass vial of 2 ml containing 1 dose, 2 doses or 5 doses.
Type I glass vial of 5 ml containing 5 doses, 10 doses or 20 doses.
Type I glass vial of 10 ml containing 10 doses, 20 doses or 50 doses.
The vial is closed with bromobutyl rubber stopper and tear-off aluminium-plastic cap.

Solvent:
Type I glass vial, containing 2 ml, 4 ml, 10 ml, 20 ml, 40 ml or 100 ml solvent.
The vial is closed with chlorobutyl rubber stopper and tear-off aluminium-plastic cap.

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.