SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MORAXEBIN NEO inj. ad us. vet.
Vaccine against bovine infectious keratoconjunctivitis, inactivated

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition – 100 ml:
Active substance: Moraxella bovis inactivata – at least 2.5 x 10^{10} CFU
Adjuvant: Algeldrati suspensio 2% (ALHYDROGEL),
Excipients: Formaldehydi solutio 35% , Thiomersalum, Nutrimento liquido, saline solution.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injection solution for parenteral use

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use,specifying the target species

Immunoprophylaxis of infectious bovine keratoconjunctivitis in cattle aged 1 months and above.
From the immunological point of view, the mass vaccination should be performed in all sensitive animals before the beginning of a grazing season.

4.3 Contraindications

At least 14-days period shall be kept between the application of any other vaccine and the vaccine mentioned above. The vaccine should be applied not later than 14 days before and after cattle planned transfer.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

The appropriate local response that disappears within 14 days on its own accord can be expected after the vaccination and revaccination with the vaccine MORAXEBIN NEO inj. ad us. vet.

4.7 Use during pregnancy, lactation or lay

It has no effect to pregnancy and lactation course. Animals being at the last pregnancy month should not be generally vaccinated (handling, restlessness, onset of antibodies, etc.).

4.8 Interaction with other medicinal products and other forms of interaction
At least 14-days period shall be kept between the application of any other vaccine and the vaccine mentioned above.

4.9 Amounts to be administered and administration route
2 ml of the vaccine twice at the interval of 14 days.
Administration route: Intramuscular into a neck musculature close to a lymph-node before a blade-bone.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
Double vaccine dose does not cause any side effects to target animals.

4.11 Withdrawal period(s)
Without withdrawal periods.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for bovidae, Cattle, Inactivated bacterial vaccines
ATCvet code: QI02AB Inactivated bacterial vaccines

After the antigen contained in the vaccine is applied into an animal's body, the specific antibodies against the infectious keratoconjunctivitis are formed and protect the immunized animal against the disease mentioned.
The immunity onset is apparent 14 days after the vaccination and lasts for 9 months.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Formaldehydi solutio 35%, Thiomersalum, Nutrimento liquido, Saline solution.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
18 months
Life after the first opening – 10 hours

6.4. Special precautions for storage
Keep in a dry and dark place at of 2 to 8°C. Do not freeze!

6.5 Nature and composition of immediate packaging
The vaccine is supplied in glass vials or plastic vials and in glass or plastic bottles hermetically sealed with rubber piercing plugs and equipped with aluminium closures. The vials containing the vaccine are placed in cardboard boxes. Approved Package Insert is attached to each package.
The vials in mass packages are placed in a cardboard box with grid.
Package size: 1 x 10 ml
1 x 20 ml,
1 x 50 ml, 12 x 50 ml, 24 x 50 ml,
1 x 100 ml, 12 x 100 ml, 20 x 100 ml
1 x 250 ml, 12 x 250 ml, 20 x 250 ml
1 x 500 ml

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

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8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT