

Lyophilisate and solvent for suspension for injection or nasal spray for cattle Live attenuated bovine respiratory syncytial virus, strain Lym-56

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT:

Marketing authorisation holder and manufacturer responsible for batch release:

Laboratorios Hipra, S.A.

Avda. la Selva 135 - Amer, 17170 (Girona) Spain

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S):

Each dose of 2 ml contains:

Active substance:

Live attenuated bovine respiratory syncytial virus, strain Lym-56 $10^{4.7-6.5}$ CCID₅₀*

*Cell culture infectious dose 50%.

Solvent.

Lyophilisate: Whitish freeze-dried lyophilisate.

Solvent: Homogeneous clear solution.

INDICATION(S):

Active immunisation of cattle to reduce virus shedding and respiratory clinical signs caused by bovine respiratory syncytial virus infection.

Onset of immunity: 21 days after administration of one dose by the nasal route.

21 days after the second dose of the two-dose intramuscular vaccination schedule.

Duration of immunity: 2 months after nasal vaccination.

6 months after intramuscular vaccination.

CONTRAINDICATIONS:

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

ADVERSE REACTIONS:

Slight alteration of faecal consistency may be commonly observed post-vaccination.

Calves may uncommonly display a peak in temperature of at least 1.7 °C two days after vaccination that resolves the next day without treatment.

Anaphylactic-type reactions which may be serious (including fatal) have been reported very rarely. In case of such reactions, appropriate symptomatic treatment should be administered.

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.

TARGET SPECIES: Cattle.

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION:

One dose is 2 ml.

Nasal use or intramuscular use.

The following doses and administration methods should be used:

Cattle from 9 days of age: Primary vaccination (nasal use): Spray 1 ml into each nostril (so the total volume administered is 2 ml). Revaccination: One intramuscular injection of 2 ml should be given 2 months after the primary vaccination, and then every 6 months after the last revaccination.

Cattle from 10 weeks of age: Primary vaccination (intramuscular injection): One intramuscular injection of 2 ml should be given, followed by a second intramuscular injection of 2 ml given 4 weeks later. Revaccination: One intramuscular injection of 2 ml should be given 6 months after completion of the primary vaccination scheme and then every 6 months after the last revaccination.

ADVICE ON CORRECT ADMINISTRATION:

Reconstitute the vaccine with the corresponding volume of solvent:

1. Peel the top off the aluminium cap on the vial containing the solvent, and withdraw 10 ml (2 ml for the 1-dose vial).
2. Inject the solvent into the vial containing the lyophilisate (freeze-dried powder).
3. Shake until the freeze-dried powder is in suspension. The 1- and 5-dose vials are now ready to use.

4. For the 25-dose vial, once the freeze-dried powder is in suspension with the 10 ml of solvent, withdraw all the suspension obtained from the vaccine vial and inject it into the vial containing the remaining solvent.

5. Shake well before use. The reconstituted vaccine is a slightly yellowish homogeneous suspension.

Avoid contamination during reconstitution and use. Use only sterile needles and syringes for administration.

For nasal use, spray the required volume of the vaccine into the animal's nostrils (1 ml in each nostril) using an intranasal applicator (droplet size: 25–220 µm). It is recommended to use a new applicator for each animal.

WITHDRAWAL PERIOD(S): Zero days.

SPECIAL STORAGE PRECAUTIONS:

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C). Protect from light.

Do not use this veterinary medicinal product and the solvent after the expiry date which is stated on the carton and the label.

Shelf life after reconstitution according to directions: use immediately.

SPECIAL WARNING(S):

Special precautions for use in animals

Vaccinate healthy animals only.

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.

Pregnancy and lactation

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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 occurred following the administration of an overdose.

Incompatibilities

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

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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED: 18/10/2022.

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

OTHER INFORMATION:

Cardboard box with 1 lyophilisate vial of 5 doses and 1 vial of 10 ml of solvent.

Cardboard box with 1 lyophilisate vial of 25 doses and 1 vial of 50 ml of solvent.

Cardboard box with 10 lyophilisate vials of 5 doses.

Cardboard box with 10 vials of 10 ml of solvent.

Cardboard box with 10 lyophilisate vials of 25 doses.

Cardboard box with 10 vials of 50 ml of solvent.

Cardboard box with 10 lyophilisate vials of 1 dose and 10 vials of 2 ml of solvent.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Number of doses in vial of lyophilisate	Volume of solvent to be used
1 dose	2 ml
5 doses	10 ml
25 doses	50 ml



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