1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NASYM lyophilisate and solvent for suspension for injection or nasal spray for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Lyophilisate:
Active substance:
Live attenuated bovine respiratory syncytial virus (BRSV), strain Lym-56..... $10^{4.7 - 6.5}$ $CCID_{50}$*
*Cell culture infectious dose 50%

Solvent:
Phosphate buffer solution

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection or nasal spray.
Lyophilisate: Whitish freeze-dried lyophilisate.
Solvent: Homogeneous clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

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

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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

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)

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.

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).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established 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 made on a case-by-case basis.

4.9 Amounts to be administered and administration route

Nasal use or intramuscular use.

Reconstitute the vaccine with the corresponding volume of solvent:

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

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.

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.

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

No adverse reactions other than those described in section 4.6 occurred following the administration of an overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunological for Bovidae, Cattle, Live viral vaccines, bovine respiratory syncytial virus (BRSV).
ATCvet code: QI02AD04.

To stimulate active immunity against bovine respiratory syncytial virus.

Reduction of respiratory clinical signs (but not a reduction of virus shedding) is observed 5 days after nasal vaccination. Full immunity is established from 21 days after nasal vaccination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Dextran
Sucrose
Gelatin
NZ amine
Sorbitol
Potassium dihydrogen phosphate
Dipotassium phosphate

Solvent:
Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Sodium chloride
Potassium chloride
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf life after reconstitution according to directions: use immediately.
Shelf life of the solvent: 5 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. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Lyophilisate (vaccine): 3 or 10 ml type I glass vials of 1, 5 or 25 doses, sealed with a bromobutyl rubber stopper and aluminium cap.

Solvent: type I glass vials of 2 ml and polyethylene (PET) vials of 10 ml or 50 ml, sealed with a bromobutyl rubber stopper and aluminium cap.

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.

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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/241/001-005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}>

10. DATE OF REVISION OF THE TEXT

<{DD/MM/YYYY}>

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

Not applicable.