ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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:

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

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Dextran
Sucrose
Gelatin
N-Z-amine
Sorbitol
Potassium dihydrogen phosphate
Dipotassium phosphate
Solvent:
Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Sodium chloride
Potassium chloride
Water for injections

Lyophilisate: Whitish freeze-dried lyophilisate.
Solvent: Homogeneous clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each 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.

3.3 Contraindications

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

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Common (1 to 10 animals / 100 animals treated):	Slight alteration of faecal consistency
Uncommon (1 to 10 animals / 1 000 animals treated):	Elevated temperature[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reaction[2]

[1]A peak in temperature of at least 1.7 °C two days after vaccination that resolves the next day without treatment.
[2]May be serious (including fatal). In case of such reactions, appropriate symptomatic treatment should be administered.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions other than those described in section 3.6 occurred following the administration of an overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.
Shelf life of the solvent: 5 years.

5.3 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.

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/241/001-005

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 29/07/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (1 x 5 doses and 1 x 25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NASYM lyophilisate and solvent for suspension for injection or nasal spray

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Live attenuated bovine respiratory syncytial virus, strain Lym-56 $10^{4.7 - 6.5}$ $CCID_{50}$*
*Cell culture infectious dose 50%

3. PACKAGE SIZE

1 vial of lyophilisate and 1 vial of solvent (5 doses)
1 vial of lyophilisate and 1 vial of solvent (25 doses)

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Nasal use or intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/19/241/001 (5 doses)
EU/2/19/241/002 (25 doses)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for lyophilisate (10 x 5 doses and 10 x 25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NASYM lyophilisate for suspension for injection or nasal spray

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Live attenuated bovine respiratory syncytial virus, strain Lym-56 $10^{4.7 - 6.5}$ $CCID_{50}$*
*Cell culture infectious dose 50%

3. PACKAGE SIZE

10 vials of lyophilisate (50 doses)
10 vials of lyophilisate (250 doses)

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Nasal use or intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/19/241/003 (5 doses)
EU/2/19/241/004 (25 doses)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for lyophilisate and solvent (10 x 1 doses and 10 x 2 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NASYM lyophilisate for suspension for injection or nasal spray
Solvent for NASYM

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Live attenuated bovine respiratory syncytial virus, strain Lym-56 $10^{4.7 - 6.5}$ $CCID_{50}$*
*Cell culture infectious dose 50%

3. PACKAGE SIZE

10 vials of lyophilisate (10 doses) and 10 vials of solvent (20 ml).

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Nasal use or intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/19/241/005

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for solvent (10 x 10 ml and 10 x 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for NASYM

2. STATEMENT OF ACTIVE SUBSTANCES

3. PACKAGE SIZE

10 vials of solvent (100 ml)
10 vials of solvent (500 ml)

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Nasal use or intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of lyophilisate (1, 5 and 25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NASYM

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose of 2 ml contains:
Live attenuated bovine respiratory syncytial virus, strain Lym-56 $10^{4.7 - 6.5}$ $CCID_{50}$

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

5. PACKAGE SIZE

1 dose
5 doses
25 doses

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent vials (2, 10 and 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for NASYM

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. PACKAGE SIZE

2 ml
10 ml
50 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each dose of 2 ml contains:

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

Lyophilisate: Whitish freeze-dried lyophilisate.
Solvent: Homogeneous clear solution.

3. Target species

Cattle.

4. Indications for use

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.

5. Contraindications

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

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
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.

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:
No adverse reactions occurred following the administration of an overdose.

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

7. Adverse events

Cattle:

Common (1 to 10 animals / 100 animals treated):
Slight alteration of faecal consistency
Uncommon (1 to 10 animals / 1 000 animals treated):
Elevated temperature[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Anaphylactic-type (severe allergic) reaction[2]

[1]A peak in temperature of at least 1.7 °C two days after vaccination that resolves the next day without treatment.
[2] May be serious (including fatal). In case of such reactions, appropriate symptomatic treatment should be administered.
Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes 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.

9. Advice on correct administration

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.

10. Withdrawal periods

Zero days.

11. 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 after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: use immediately.

12. Special precautions for disposal

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers: EU/2/19/241/001-005

Pack sizes:
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.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 AMER (Girona) SPAIN
TEL: +34 972 43 06 60

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

Local representatives and contact details to report suspected adverse reactions:

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