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:

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.

ANNEX II

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substance

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

Laboratorios Hipra, S.A.
Carretera C-63 Km 48.300
Polígon Industrial El Rieral,
17170 Amer (Girona)
Spain

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients listed in section 6.1 of the SPC are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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 for cattle

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%
000

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection or nasal spray

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nasal use or intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/241/001-002

17. MANUFACTURER'S BATCH NUMBER

Batch {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 for cattle

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. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection or nasal spray

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nasal use or intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/241/003-004

17. MANUFACTURER'S BATCH NUMBER

Batch {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 for cattle
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. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection or nasal spray

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nasal use or intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/241/005

17. MANUFACTURER'S BATCH NUMBER

Batch {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. PHARMACEUTICAL FORM

Solvent for suspension for injection or nasal spray

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nasal use or intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {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 lyophilisate and solvent for suspension for injection or nasal spray for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose
5 doses
25 doses

4. ROUTE(S) OF ADMINISTRATION

Nasal use or intramuscular use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2 ml
10 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

1. 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. 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..... $10^{4.7 - 6.5}$ $CCID_{50}$*
*Cell culture infectious dose 50%

Solvent:
Phosphate buffer solution

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

4. 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.

5. CONTRAINDICATIONS

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

6. 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.

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.

7. TARGET SPECIES

Cattle.

8. 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.

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 PERIOD(S)

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.
Shelf life after reconstitution according to directions: use immediately.

12. 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.

13. 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. 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.

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