PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 bottle of 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

*Mannheimia haemolytica** type A1 antigen: leucotoxin minimum of .....68 ELISA.U

Thiomersal .....0.2 mg
Aluminium (as hydroxide) .....4.2 mg
Excipient q.s. 1 dose of 2 ml

* *Mannheimia haemolytica* was formerly called *PAsteurella haemolytica.*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

2-ml bottle, 1 dose

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica** A1 induced respiratory disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C, protected from light. Do not freeze.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4173

VPA 10454/028/001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 bottle of 5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

*Mannheimia haemolytica** type A1 antigen: leucotoxin minimum of .....68 ELISA.U

Thiomersal .....0.2 mg
Aluminium (as hydroxide) .....4.2 mg
Excipient q.s. 1 dose of 2 ml

* *Mannheimia haemolytica* was formerly called *Pasteurella haemolytica.*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10-ml bottle, 5 doses

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica** A1 induced respiratory disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C, protected from light. Do not freeze.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4173

VPA 10454/028/001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 bottle of 10 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

*Mannheimia haemolytica** type A1 antigen: leucotoxin minimum of .....68 ELISA.U

Thiomersal .....0.2 mg
Aluminium (as hydroxide) .....4.2 mg
Excipient q.s. 1 dose of 2 ml

* *Mannheimia haemolytica* was formerly called *Pasteurella haemolytica.*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

20-ml bottle, 10 doses

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica** A1 induced respiratory disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C, protected from light. Do not freeze.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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

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To be supplied only on veterinary prescription

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Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4173

VPA 10454/028/001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 bottles of 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

*Mannheimia haemolytica** type A1 antigen: leucotoxin minimum of .....68 ELISA.U

Thiomersal .....0.2 mg
Aluminium (as hydroxide) .....4.2 mg
Excipient q.s. 1 dose of 2 ml

* *Mannheimia haemolytica* was formerly called *Pasteurella haemolytica.*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 bottles of 2 ml, 10 x 1 dose

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica** A1 induced respiratory disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C, protected from light. Do not freeze

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4173

VPA 10454/028/001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 bottles of 5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

*Mannheimia haemolytica** type A1 antigen: leucotoxin minimum of .....68 ELISA.U

Thiomersal .....0.2 mg
Aluminium (as hydroxide) .....4.2 mg
Excipient q.s. 1 dose of 2 ml

* *Mannheimia haemolytica* was formerly called *Pasteurella haemolytica.*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 bottles of 10 ml, 10 x 5 doses

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica** A1 induced respiratory disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C, protected from light. Do not freeze.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4173

VPA 10454/028/001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 bottles of 10 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

*Mannheimia haemolytica** type A1 antigen: leucotoxin minimum of .....68 ELISA.U

Thiomersal .....0.2 mg
Aluminium (as hydroxide) .....4.2 mg
Excipient q.s. 1 dose of 2 ml

* *Mannheimia haemolytica* was formerly called *Pasteurella haemolytica.*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 bottles of 20 ml, 10 x 10 doses

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica** A1 induced respiratory disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C, protected from light. Do not freeze.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4173

VPA 10454/028/001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 50 bottles of 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

*Mannheimia haemolytica** type A1 antigen: leucotoxin minimum of .....68 ELISA.U

Thiomersal .....0.2 mg
Aluminium (as hydroxide) .....4.2 mg
Excipient q.s. 1 dose of 2 ml

* *Mannheimia haemolytica* was formerly called *Pasteurella haemolytica.*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 bottles of 2 ml, 50 x 1 dose

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica** A1 induced respiratory disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C, protected from light. Do not freeze

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4173

VPA 10454/028/001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 100 bottles of 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

*Mannheimia haemolytica** type A1 antigen: leucotoxin minimum of .....68 ELISA.U

Thiomersal .....0.2 mg
Aluminium (as hydroxide) .....4.2 mg
Excipient q.s. 1 dose of 2 ml

* *Mannheimia haemolytica was formerly* called *Pasteurella haemolytica.*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 bottles of 2 ml, 100 x 1 dose

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica** A1 induced respiratory disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C, protected from light. Do not freeze.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4173

VPA 10454/028/001

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov
Suspension for Injection
Cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Mannheimia haemolytica type A1 antigen: leucotoxin

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

2-ml bottle, 1 dose

4. ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

Batch

7. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov
Suspension for Injection
Cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Mannheimia haemolytica type A1 antigen: leucotoxin

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

10-ml bottle, 5 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

Batch

7. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 10 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov
Suspension for Injection
Cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Mannheimia haemolytica type A1 antigen: leucotoxin

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

20-ml bottle, 10 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous route.

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

Batch

7. EXPIRY DATE

Exp.:

Any open bottle should be used within one working day.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET
Bovalto Pastobov

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

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer for the batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Portes des Alpes
Rue de l'Aviation
69800 Saint Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Pastobov
Suspension for injection – Milky beige
Cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:
*Mannheimia haemolytica** type A1 antigen: leucotoxin minimum of .....68 ELISA.U

* *Mannheimia haemolytica* was formerly called *Pasteurella haemolytica*

Adjuvant(s):
Aluminium (as hydroxide) .....4.2 mg
Thiomersal .....0.2 mg

Excipient(s):
Excipient ..... q.s.p. 1 dose of 2 ml

4. INDICATION(S)

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica* induced respiratory disease.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Vaccination by the subcutaneous route is followed by a limited 2-5 cm local reaction (oedema developing as a nodule) that regresses within 3 weeks.

Vaccination by the intramuscular route can cause a transient, diffuse oedema and slight local reaction up to 5 cm diameter that regresses within 1-2 weeks.
After subcutaneous and intramuscular injection granulomas up to 5 cm diameter may occur.
Vaccination (by the subcutaneous or intramuscular route) may sometimes induce slight (1°C) transient (24-72 hours) hyperthermia and also hypersensitivity reactions.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

Intramuscular or subcutaneous route.

Inject one 2-ml dose according to the following schedule:

- Primary vaccination preferably before the risk period.
  First injection: at the minimum age of 4 weeks.
  Second injection: 21-28 days later.

- Booster vaccination injection preferably before each risk period.
  One injection no later than one year after the previous vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Shake prior to use.
Apply usual aseptic procedures.
Vaccinate only healthy animals.
Apply usual procedures for the handling of the animals.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport between 2°C and 8°C, protected from light. Do not freeze.
Any open bottle should be used within one working day.
Do not use after the expiry date stated on the bottle.

12. SPECIAL WARNING(S)

Special precautions for animals:

Pregnancy: Can be used during pregnancy.

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

Vaccination with a double dose by the subcutaneous route is followed by a limited 2-5 cm local reaction (oedema developing as a nodule) that regresses within 3 weeks. Vaccination with a double dose by the intramuscular route can cause a transient, diffuse oedema and slight local reaction up to 5 cm diameter that regresses within 1-2 weeks. After subcutaneous and intramuscular injection granulomas up to 5 cm diameter may occur. For both subcutaneous and intramuscular route, slight (1°C) transient (24-72 hours) hyperthermia could be observed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused product or waste materials should be disposed of in accordance with national requirements.

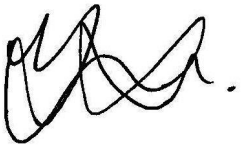
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2020

15. OTHER INFORMATION

Adjuvanted, inactivated vaccine against *Mannheimia haemolytica** A1 respiratory infections of cattle.
Box of 1 dose-glass bottle.
Box of 5 dose-glass bottle.
Box of 10 dose-glass bottle.
Box of 10 glass bottles of 1 dose.
Box of 50 glass bottles of 1 dose.
Box of 100 glass bottles of 1 dose.
Box of 10 glass bottles of 5 doses.
Box of 10 glass bottles of 10 doses.

Not all pack sizes may be marketed.



Approved: 27 May 2020