*[Version 8.2,01/2021]*

# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**{LABEL}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS SOMNI/Lkt Emulsion for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

*Mannheimia haemolytica* Biotype A serotype A1, inactivated cell free suspension containing leukotoxoid: ELISA > 2.8 (*)/doseInactivated *Histophilus somni* Bailie strain: MAT > 3.3(**)/dose
(*) A minimum of 80 % of vaccinated rabbits show ELISA value of > 2.0; the mean ELISA is >2.8.
(**) A minimum of (80 % of vaccinated rabbits show a $\log_2$ MAT value of ≥ 3.0; the mean $\log_2$ MAT >3.3
Liquid paraffin: .....18.2 mg/dose
Thiomersal: .....0.2 mg/dose

## 3. PHARMACEUTICAL FORM

Emulsion for injection.

## 4. PACKAGE SIZE

50 doses

## 5. TARGET SPECIES

Cattle from 2 months of age.

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous route.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

Withdrawal period: 0 days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous

## 10. EXPIRY DATE

EXP {month/year}
Once opened, use by 10 hours

## 11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

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

## 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)

Vm 17533/4005

## 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**{LABEL}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS SOMNI/Lkt Emulsion for injection

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

*Mannheimia haemolytica* Biotype A serotype A1, inactivated cell free suspension containing leukotoxoid: ELISA > 2.8 (*)/dose .
Inactivated *Histophilus somni* Bailie strain: MAT > 3.3(**)/dose
(*) A minimum of 80 % of vaccinated rabbits show ELISA value of > 2.0; the mean ELISA is >2.8.
(**) A minimum of (80 % of vaccinated rabbits show a $\log_2$ MAT value of ≥ 3.0; the mean $\log_2$ MAT >3.3
Liquid paraffin: .....18.2 mg/dose
Thiomersal: .....0.2 mg/dose

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

10 doses

## 4. ROUTE(S) OF ADMINISTRATION

Subcutaneous.

## 5. WITHDRAWAL PERIOD(S)

Zero days.

## 6. BATCH NUMBER

Batch {number}

## 7. EXPIRY DATE

EXP {mmm/yyyy}
Once/opened, use by 10 hours.

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**{CARDBOARD BOX}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS SOMNI/Lkt Emulsion for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

*Mannheimia haemolytica* Biotype A serotype A1, inactivated cell free suspension containing leukotoxoid: ELISA > 2.8 (*)/doseInactivated *Histophilus somni* Bailie strain: MAT > 3.3(**)/dose
(*) A minimum of 80 % of vaccinated rabbits show ELISA value of > 2.0; the mean ELISA is >2.8.
(**) A minimum of (80 % of vaccinated rabbits show a $\log_2$ MAT value of ≥ 3.0; the mean $\log_2$ MAT >3.3
Liquid paraffin: .....18.2 mg/dose
Thiomersal: .....0.2 mg/dose

## 3. PHARMACEUTICAL FORM

Emulsion for injection.

## 4. PACKAGE SIZE

50 doses (100 ml)
10 doses (20 ml)

## 5. TARGET SPECIES

Cattle from 2 months of age.

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Cattle: 2 ml/animal.
Administer one dose (2 ml) per calf, at 2 months of age. This 2 ml dose should be repeated after 21 days.
Shake well before use.

## 8. WITHDRAWAL PERIOD(S)

Zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous.

## 10. EXPIRY DATE

EXP: {mmm/yyyy}
Once opened, use by 10 hours

## 11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

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

Dispose of waste material in accordance with local 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 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)

Vm 17533/4005

## 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:
# HIPRABOVIS SOMNI/Lkt emulsion for injection 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
17170- AMER (Girona) SPAIN

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS SOMNI/Lkt. Emulsion for injection for cattle

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

*Mannheimia haemolytica* Biotype A serotype A1, inactivated cell free suspension containing leukotoxoid: ELISA > 2.8 (*)/dose.
Inactivated *Histophilus somni* Bailie strain: MAT > 3.3 (**)/dose
(*) A minimum of 80 % of vaccinated rabbits show ELISA value of > 2.0; the mean ELISA is >2.8.
(**) A minimum of (80 % of vaccinated rabbits show a $\log_2$ MAT value of ≥ 3.0; the mean $\log_2$ MAT >3.3
Liquid paraffin: 18.2 mg/dose
Thiomersal: 0.2 mg/dose

## 4. INDICATION(S)

To reduce the clinical signs and lung lesions caused by *Mannheimia haemolytica* serotype A1 and *Histophilus somni* in calves from 2 months of age.

**Onset of immunity**:
3 weeks.

**Duration of protection:**
Not demonstrated.

## 5. CONTRAINDICATIONS

Do not vaccinate unhealthy animals.
Do not use in case of hypersensitivity to the active substances, to the adjuvant or to any of the excipients.

## 6. ADVERSE REACTIONS

Very common: A transient rise in temperature (up to 2 ºC) after each vaccination can occur but this resolves after 4 days.Vaccinated animals might show a local swelling at the injection site of 1 to 7 cm after administration of the vaccine. This swelling will have disappeared or be clearly reduced in size by 14 days post vaccination however in some cases swelling may persist for up to 4 weeks after the second administration.

Common: Mild apathy, anorexia and/or depression may be observed after each injection but these resolve within 4 days.

Very rare: Anaphylactic-type reactions may occur in some sensitive animals, which may be life-threatening.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated).
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious 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 from 2 months of age.

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

For subcutaneous use.
Cattle: 2 ml / animal.
Recommended vaccination scheme: Administer one dose (2 ml) per calf, at 2 months of age. This 2 ml dose should be repeated after 21 days. Vaccinate calves by subcutaneous injection in the prescapular area. It is preferable to administer the second dose on alternate sides.

Vaccination is recommended to be used before stress periods (shipping, allotments…). The vaccination scheme should be completed 3 weeks before such periods. Protection has not been demonstrated if vaccination scheme is completed earlier than 3 weeks before stress periods

## 9. ADVICE ON CORRECT ADMINISTRATION

The vaccine should be allowed to warm to a temperature between 15 - 20°C before administration. Shake before use. Avoid the introduction of contamination during use. Use only sterile needles and syringes for administration.

## 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).
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after first opening the container: 10 hours.

## 12. SPECIAL WARNING(S)

Special precautions for use in animals
Do not use in animals which are underweight for their age.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy and lactation:Do not use during pregnancy.
Do not use during 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 effects other than those mentioned in "Adverse reactions" section were observed after administration of twice the recommended dose.

Incompatibilities
Do not mix with any other 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 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

December 2022

## 15. OTHER INFORMATION

Pack sizes:
10 doses vial.
50 doses bottle.

Not all pack sizes may be marketed.

FOR ANIMAL TREATMENT ONLY

Vm 17533/4005