ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with one glass vial of 10 doses.
Cardboard box with one glass bottle of 50 doses.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS SOMNI/Lkt emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Mannheimia haemolytica, serotype A1, strain 2806, leucotoxoid: ELISA > 2.8 (*)/dose.
Histophilus somni, strain Bailie, inactivated: 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

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 10 hours.

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 SA

14. MARKETING AUTHORISATION NUMBERS

Vm 17533/3006

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for glass bottle of 50 doses (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS SOMNI/Lkt emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Mannheimia haemolytica, serotype A1, strain 2806, leucotoxoid: ELISA > 2.8 (*)/dose
Histophilus somni, strain Bailie, inactivated 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

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 10 hours

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Hipra SA

9. BATCH NUMBER

Lot {number}

50 doses (100 ml)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for glass vial of 10 doses (20 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS SOMNI/Lkt

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Mannheimia haemolytica, serotype A1, strain 2806, leucotoxoid: ELISA > 2.8 /dose
Histophilus somni, strain Bailie, inactivated: MAT > 3.3/dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 10 hours.

10 doses (20 ml)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

HIPRABOVIS SOMNI/Lkt emulsion for injection for cattle

2. Composition

Each dose (2 ml) contains:

Active substances:
Mannheimia haemolytica, serotype A1, strain 2806, leucotoxoid: ELISA > 2.8 (*)
Histophilus somni, strain Bailie, inactivated: MAT > 3.3 (**)
(*) 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

Adjuvant:
Liquid paraffin: 18.2 mg

Excipient:
Thiomersal: 0.2 mg

Ivory-coloured homogeneous emulsion.

3. Target species

Cattle.

4. Indications for use

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 immunity: Has not been established.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances, to the adjuvant or to any of the excipients.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
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.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Do not use 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 effects other than those mentioned in ‘Adverse events’ section were observed after administration of twice the recommended dose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]
Common (1 to 10 animals / 100 animals treated):	Apathy[3], Anorexia[3], Depression[3]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reaction (severe allergic reaction)[4]

[1] Up to 2 ºC, resolves after 4 days.
[2] Diameter of 1 to 7 cm, will disappear or be clearly reduced in size within 14 days. May persist for up to 4 weeks after second administration.
[3] Mild, resolves within 4 days.
[4] Appropriate symptomatic treatment such as antihistamines or cortisone or in more severe cases adrenaline should be given.

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:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

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 periods

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.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 10 hours.

12. Special precautions for disposal

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.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number: Vm 17533/3006

Pack sizes:
Cardboard box with one glass vial of 10 doses.
Cardboard box with one glass bottle of 50 doses.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

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

Laboratorios Hipra SA
Avda. la Selva, 135
17170 Amer (Girona)
Spain
Tel. +34 972 43 06 60

Local representatives and contact details to report suspected adverse reactions:

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

Hipra UK, Ltd.
Innovation Center, Office 503
BioCity Nottingham
Pennyfoot Street
Nottingham
NG1 1GF

17. Other information

POM-V

Gavin Hall
Approved: 16 April 2025