1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS SOMNI/Lkt emulsion for injection for cattle

2. QUALITATIVE AND QUANTITATIVE 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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product.**
Thiomersal	0.2 mg
Sorbitan monooleate	
Polysorbate 80	
Sodium alginate	
Calcium chloride, dihydrate	
Simeticone	
Water for injections	
Polymyxin B	

Ivory-coloured homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances, to the adjuvant 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:

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 veterinary medicinal 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.

3.6 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[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 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:
Do not use 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

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.

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.

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.

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

No effects other than those mentioned in section 3.6 were observed after administration of twice the recommended dose.

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: QI02AB.

To stimulate active immunity against *Mannheimia haemolytica* A1 and *Histophilus somni.*

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

The container consists of 20 ml (10 doses) Type I colourless glass vials and 100 ml (50 doses) Type II colourless glass vials, Type I rubber stoppers and aluminium caps.

Package 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.

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)

VPA10846/005/001

8. DATE OF FIRST AUTHORISATION

27/10/2005

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

25/10/2024

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).