Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS SOMNI/Lkt
Emulsion for injection for cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Mannheimia haemolytica Biotype A serotype A1, inactivated cell free suspension containing leukoxid Ph. Eur.	- 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

Adjuvant:

Liquid paraffin	18.2	mg/dose

Excipients:

Thiomersal	0.2	mg/dose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection.
Ivory-coloured homogeneous emulsion.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle from 2 months of age.

4.2 Indications for use, specifying the 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 protection:
Not demonstrated.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

Very common: A transient rise in temperature (up to 2°C) 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. In such cases, appropriate symptomatic treatment such as antihistamines or cortisone or in more severe cases adrenaline should be given.

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

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during pregnancy.
Lactation:
Do not use during 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

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No effects other than those mentioned in section 4.6 were observed after administration of twice the recommended dose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for bovidae, cattle, inactivated bacterial vaccines.
ATC vet code: QI02AB.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal.
Liquid paraffin.
Sorbitan monooleate.
Polysorbate 80.
Sodium alginate.
Calcium chloride, dihydrate.
Simeticone.
Water for injections.
Polymyxin B

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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.

6.4 Special precautions for storage

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

6.5 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 with a rubber stopper and aluminium cap.
- Cardboard box with one glass bottle of 50 doses with a rubber stopper and aluminium cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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.
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10846/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal of the last authorisation: 27th October 2010

10 DATE OF REVISION OF THE TEXT

December 2014