1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIMCO emulsion for injection for ewes and female goats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Active substance:
Inactivated *Staphylococcus aureus*, SP140 CP**8 strain, expressing Biofilm components ≥ 8.98 SaCC*
* *Staphylococcus aureus* Cell Count in $\log_{10}$.
** CP: capsular polysaccharide

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**
Benzyl alcohol	21 mg
Sorbitan monooleate	
Polysorbate 80	
Sodium alginate	
Calcium chloride, dihydrate	
Simethicone	
Sodium chloride	
Potassium chloride	
Disodium phosphate dodecahydrate	
Potassium dihydrogen phosphate	
Water for injections	

Ivory-coloured homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (ewes) and goats (adult females).

3.2 Indications for use for each target species

For active immunisation of healthy ewes in flocks with recurring mastitis problems, to reduce the incidence of sub-clinical mastitis (reduction of udder lesions, somatic cell count and *S. aureus* count) caused by *Staphylococcus aureus*.

For active immunisation of healthy female goats in herds with recurring mastitis problems, to reduce the incidence of sub-clinical mastitis caused by *Staphylococcus aureus* and/or Coagulase-Negative Staphylococci; when clinical mastitis caused by Coagulase-Negative Staphylococci* however occurs, the severity of clinical signs (udder and milk aspect) is reduced.
*(*Determination of the CNS species has not been performed)*

- Onset of immunity:
  Ewes: 6 weeks
  Goats: has not been established (see section 4)
- Duration of immunity: has not been established

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Immunisation has to be considered as one component in a complex mastitis control programme that addresses all important udder health factors (e.g. milking technique, dry-off and breeding management, hygiene, nutrition, housing, bedding, animal comfort, air and water quality, health monitoring) and other management practices.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

Ewes and adult female goats:

Very common	Injection site swelling[1].

(>1 animal / 10 animals treated):	
Common (1 to 10 animals / 100 animals treated):	Injection site swelling[2], Elevated temperature[3].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction[4], apathy[5], anorexia, recumbency.

[1]Swelling of less than 2 cm in diameter which disappears within 12 days at most.
[2]Swelling higher than 5 cm in diameter which resolves within 3 days at most.
[3]Transient reaction of up to 1.8ºC occurred between the first 4 hours and 3 days after injection, which spontaneously resolves within some days without compromising animal health status.
[4]Reactions might be life-threatening and/or cause abortion. In such cases, appropriate and rapid symptomatic treatment should be administered.
[5]Mild.

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:

Can be used 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

Intramuscular use.
Allow the vaccine to reach a temperature of +15 ºC to +25 ºC before administration.
Shake before use.
Minimum age at vaccination: 8 months.

Basic vaccination: Administer one dose (2 ml) by deep intramuscular injection in the neck muscles at 5 weeks before the expected parturition date and 3 weeks after the first dose, administer a second dose.

Revaccination: The basic vaccination scheme is to be repeated prior to each lactation.

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

Transient increase in body temperature of about 1 ºC in some animals up to 1.8 ºC may occur in the first 24-48 hours after injection of a 2-fold dose.

Hard spots up to 5 cm in diameter which disappear within 7-9 days may be observed after injection of a 2-fold 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: QI03AB

To stimulate active immunisation against *Staphylococcus aureus* in ewes.

To stimulate active immunisation against *Staphylococcus aureus* and/or Coagulase-Negative Staphylococci in female goats.

The full immunisation scheme in goats induces a serological response from 3 weeks after vaccination. The relevance of these antibody levels to the protection afforded by the vaccine has not been determined experimentally.

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 at +15 ºC to +25 ºC.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

10 ml, 50 ml and 100 ml Type I colourless glass and Polyethylene (PET) vials, closed with rubber stoppers and aluminium caps.

Pack sizes:
Cardboard box with 1 glass vial of 5 doses (10 ml).
Cardboard box with 1 glass vial of 25 doses (50 ml).
Cardboard box with 1 glass vial of 50 doses (100 ml).

Cardboard box with 1 PET vial of 5 doses (10 ml).
Cardboard box with 1 PET vial of 25 doses (50 ml).
Cardboard box with 1 PET vial of 50 doses (100 ml).

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)

VPA10846/016/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 29/09/2017

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

17/05/2019

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).