Summary of Product Characteristics

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
Excipient:	
Benzyl alcohol	21 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection.
Ivory-coloured homogeneous.

4 CLINICAL PARTICULARS

4.1 Target Species

Ewes and adult female goats.

4.2 Indications for use, specifying the 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 goatsin 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)*

The onset of immunity in ewes is 6 weeks.
The onset of immunity in goats has not been established (see section 5).
The duration of immunity in ewes and goats has not been established.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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 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)

- Slight swelling at the injection site of less than 2 cm in diameter, which disappears within 12 days at most, occurred very commonly during clinical studies.

- Swelling at the injection site higher than 5 cm in diameter, which resolves within 3 days at most, occurred commonly during clinical studies.

- Transient increase in body temperature of up to 1.8 ºC occurred commonly between the first 4 hours and 3 days after injection during clinical studies, which spontaneously resolves within some days without compromising animal health status.

- Anaphylactic-type reactions, which might be life-threatening and/or cause abortion occurred very rarely based on post-authorisation pharmacovigilance reporting. Under these circumstances, appropriate and rapid symptomatic treatment should be administered.

- Mild apathy, anorexia and/or recumbency occurred very rarely after administration of the vaccine based on post-authorisation pharmacovigilance reporting.

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

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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

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.
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.

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

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

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.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccines.
ATC vet 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol.
Liquid paraffin.
Sorbitan monooleate.
Polysorbate 80.
Sodium alginate.
Calcium chloride, dihydrate.
Simethicone.
Sodium chloride.
Potassium chloride.
Disodium phosphate dodecahydrate.
Potassium dihydrogen phosphate.
Water for injections.

6.2 Major 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).
Protect from light.
Do not freeze.
Once broached use by 10 hours stored at +15 ºC to +25 ºC.

6.5 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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Laboratorios Hipra S.A.
Avda. La Selva 135
17170 - Amer (Girona)
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10846/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th September 2017
Date of last renewal: 17th May 2019

10 DATE OF REVISION OF THE TEXT

May 2019