ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes (5, 25 or 50 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIMCO emulsion for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:

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

3. PACKAGE SIZE

5 doses (10 ml).
25 doses (50 ml).
50 doses (100 ml).

4. TARGET SPECIES

Ewes and adult female goats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours stored at +15 ºC to +25 ºC.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 ºC - 8 ºC).

Protect from light.
Do not freeze.

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, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 17533/3001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vaccine vial of 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIMCO emulsion for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:

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

3. TARGET SPECIES

Ewes and adult female goats

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours stored at +15 ºC to +25 ºC.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vaccine vial of 5 and 25 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIMCO.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

One dose (2 ml) contains:

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours stored at +15 ºC to +25 ºC.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses (10 ml).
25 doses (50 ml).

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

VIMCO emulsion for injection for ewes and female goats.

2. Composition

One dose (2 ml) contains:

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:
Benzyl alcohol……. 21 mg

Ivory-coloured homogenous emulsion.

3. Target species

Sheep (ewes) and goats (adult females).

4. Indications for use

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
- Duration of immunity: has not been established

5. Contraindications

None.

6. Special warnings

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.

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.

Pregnancy and lactation:
Can be used 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:
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.

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

7. Adverse events

Ewes and adult female goats:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1].
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 (Severe allergic reaction)[4], apathy[5], anorexia (Loss of appetite), recumbency (Lying down).

[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 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:

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

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.

9. Advice on correct administration

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC - 8 ºC).
Protect from light.
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 10 hours stored at +15 ºC to +25 ºC.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number:
Vm 17533/3001

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.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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

LABORATORIOS HIPRA, S.A.
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 and Ireland Ltd
Innovation Centre
BioCity Nottingham
Pennyfoot Street
Nottingham
NG1 1GF

17. Other information

Approved 21 September 2023