ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

CARDBOARD BOXES AND 50-DOSES LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIMCO emulsion for injection for ewes and female goats.

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
Liquid paraffin……. .....18.2 mg
Benzyl alcohol…….....21 mg

3. PHARMACEUTICAL FORM

Emulsion for injection.
Ivory-coloured homogeneous.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Ewes and adult female goats.

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use by 10 hours stored at +15 ºC to +25 ºC.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. -To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 17533/5016

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIMCO emulsion for injection for ewes and female goats.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use by 10 hours stored at +15 ºC to +25 ºC.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
VIMCO emulsion for injection for ewes and female goats.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Laboratorios Hipra S.A.
Avda. La Selva, 135
17170 Amer (Girona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIMCO emulsion for injection for ewes and female goats.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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
Liquid paraffin……. .....18.2 mg
Benzyl alcohol…….....21 mg

Emulsion for injection.
Ivory-coloured homogeneous.

4. INDICATION(S)

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)*

The onset of immunity in ewes is 6 weeks.
The onset of immunity in goats has not been established.
The duration of immunity in ewes and goats has not been established.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

- 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).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Ewes and adult female goats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.
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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

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

12. SPECIAL WARNING(S)

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 (symptoms, emergency procedures, 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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2023

15. OTHER INFORMATION

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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 21 September 2023