ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UBAC emulsion for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Active substances:
Lipoteichoic acid (LTA) from Biofilm Adhesion Component (BAC) of *Streptococcus uberis*, strain 5616 ≥ 1 RPU*
* Relative Potency Units (ELISA)

Adjuvants:
Montanide ISA 907.1 mg
Monophosphoryl Lipid A (MPLA)

Excipients:

Qualitative composition of excipients and other constituents
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Water for injections

White homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For active immunisation of healthy cows and heifers to reduce the incidence of clinical intramammary infections caused by *Streptococcus uberis*, to reduce the somatic cell count in *Streptococcus uberis* positive quarter milk samples and to reduce milk production losses caused by *Streptococcus uberis* intramammary infections.

Onset of immunity: approximately 36 days after the second dose.
Duration of immunity: approximately the first 5 months of lactation.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The whole herd should be immunised.

Immunisation has to be considered as one component in a complex intramammary infection control program that addresses all important udder health factors (e.g. milking technique, dry-off and breeding management, hygiene, nutrition, housing, bedding, cow comfort, air and water quality and 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

Cattle:

Very common (> 1 animal / 10 animals treated):	Injection site swelling[1] Elevated temperature[2]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reaction[3]

[1]Local swelling more than 5 cm in diameter is very common after administration of the vaccine. This swelling will have disappeared or be clearly reduced in size by 17 days post vaccination. However, in some cases, swelling may persist for up to 4 weeks.
[2]A transient increase in rectal temperature (mean increase of 1 °C but may be up to 2 °C in individual animals) may occur in the first 24 hours after injection.

[3]Anaphylactic-type reactions (e.g. oedema) which might be life-threatening, may occur in some sensitive animals. Under these circumstances, appropriate symptomatic treatment should be administered.

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.

The injections should be preferably administered on the alternate sides of the neck. Allow the vaccine to reach a temperature of 15 °C to 25 °C before administration. Shake before use.

Administer one dose (2 ml) by deep intramuscular injection in the neck muscles according to the following immunisation program:
- First dose at approximately 60 days before the expected parturition date
- Second dose at least 21 days before the expected parturition date
- Third dose should be administered about 15 days after the calving.

Protection of animals not vaccinated following this program has not been demonstrated. This should be considered in case of herd vaccination.

The full immunisation program should be repeated with each gestation.

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

No information is available.

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: QI02AB18.

Subunit vaccine to stimulate active immunity against *Streptococcus uberis*.

In a multicentre field study, the incidence of new cases of *Streptococcus uberis* clinical intramammary infection in the group vaccinated with UBAC was 50 % lower than the incidence in the placebo group (6.1 % versus 12.2 %) which was statistically significantly different ($p = 0.012$). Bearing in mind that some cows had suffered more than one episode of *Streptococcus uberis* clinical intramammary infection, the incidence of cows with clinical intramammary infection was 52.5 % lower in the vaccinated group than those of the placebo group (4.7 % versus 9.9 %), with a statistical significance of $p < 0.017$.

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: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I colourless glass vials of 3 ml.
Polyethylene (PET) vials of 10, 50 and 100 ml.
The vials are closed with a rubber stopper and aluminium cap.

Pack sizes:
Cardboard box with 20 glass vials of 1 dose (2 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)

EU/2/18/227/001-004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 26/07/2018.

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

{DD/MM/YYYY}

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 20 glass vials of 1 dose
Cardboard box with 1 PET vial of 5, 25 and 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UBAC emulsion for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:
Lipoteichoic acid (LTA) from Biofilm Adhesion Component (BAC) of *Streptococcus uberis*, strain 5616 ≥ 1 RPU *
* Relative Potency Units (ELISA)

3. PACKAGE SIZE

20 x 1 dose (1 vial of 2 ml).
5 doses (1 vial of 10 ml).
25 doses (1 vial of 50 ml).
50 doses (1 vial of 100 ml).

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

EU/2/18/227/001 (1 dose)
EU/2/18/227/002 (5 dose)
EU/2/18/227/003 (25 dose)
EU/2/18/227/004 (50 dose)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 25 and 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UBAC emulsion for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:
Lipoteichoic acid (LTA) from Biofilm Adhesion Component (BAC) of *Streptococcus uberis*, strain 5616 ≥ 1 RPU *
* Relative Potency Units (ELISA)

3. TARGET SPECIES

Cattle

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 immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

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

25 doses (50 ml)
50 doses (100 ml)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label 1 dose and 5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UBAC

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

LTA from BAC of *Streptococcus uberis*, strain 5616 Relative Potency ≥ 1 RPU

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

5. PACKAGE SIZE

1 dose (2 ml)
5 doses (10 ml)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

UBAC emulsion for injection for cattle

2. Composition

One dose (2 ml) contains:

Active substances:
Lipoteichoic acid (LTA) from Biofilm Adhesion Component (BAC) of *Streptococcus uberis*, strain 5616 ≥ 1 RPU *
* Relative Potency Units (ELISA)

Adjuvant:
Montanide ISA 907.1 mg
Monophosphoryl Lipid A (MPLA)

White homogeneous emulsion.

3. Target species

Cattle.

4. Indications for use

For active immunisation of healthy cows and heifers to reduce the incidence of clinical intramammary infections caused by *Streptococcus uberis*, to reduce the somatic cell count in *Streptococcus uberis* positive quarter milk samples and to reduce milk production losses caused by *Streptococcus uberis* intramammary infections.

Onset of immunity: approximately 36 days after the second dose.
Duration of immunity: approximately the first 5 months of lactation.

5. Contraindications

None.

6. Special warnings

Special precautions for safe use in the target species:
Vaccinate healthy animals only.

The whole herd should be immunised.
Immunisation has to be considered as one component in a complex mastitis intramammary infection control program that addresses all important udder health factors (e.g. milking technique, dry-off and breeding management, hygiene, nutrition, housing, bedding, cow comfort, air and water quality and 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.

Special precautions for the protection of the environment:
Not applicable.

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:
No information is available.

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

7. Adverse events

Cattle:

Very common (> 1 animal / 10 animals treated):
Injection site swelling[1] Elevated temperature[2]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
Anaphylactic-type reaction (severe allergic reaction)[3]

[1]Local swelling more than 5 cm in diameter is very common after administration of the vaccine. This swelling will have disappeared or be clearly reduced in size by 17 days post vaccination. However, in some cases, swelling may persist for up to 4 weeks.
[2]A transient increase in rectal temperature (mean increase of 1 °C but may be up to 2 °C in individual animals) may occur in the first 24 hours after injection.
[3]Anaphylactic-type reactions (e.g. oedema) which might be life-threatening, may occur in some sensitive animals. Under these circumstances, appropriate symptomatic treatment should be administered.

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: {national system details}.

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

Intramuscular use.
Administer one dose (2 ml) by deep intramuscular injection in the neck muscles according to the following immunisation program:
- First dose at approximately 60 days before the expected parturition date
- Second dose at least 21 days before the expected parturition date
- Third dose should be administered about 15 days after the calving.

Protection of animals not vaccinated following this program has not been demonstrated. This should be considered in case of herd vaccination.

The full immunisation program should be repeated with each gestation.

9. Advice on correct administration

The injections should be preferably administered on the alternate sides of the neck. Allow the vaccine to reach a temperature of 15 C to 25 °C before administration. Shake before use.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

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 immediate packaging: use immediately.

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 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 numbers: EU/2/18/227/001-004.

Pack sizes:
Cardboard box with 20 glass vials of 1 dose (2 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.

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17. Other information

In a multicentre field study, the incidence of new cases of *Streptococcus uberis* clinical intramammary infection in the group vaccinated with UBAC was 50 % lower than the incidence in the placebo group (6.1 % versus 12.2 %) which was statistically significantly different ($p = 0.012$). Bearing in mind that some cows had suffered more than one episode of *Streptococcus uberis* clinical intramammary infection, the incidence of cows with clinical intramammary infection was 52.5 % lower in the vaccinated group than those of the placebo group (4.7 % versus 9.9 %), with a statistical significance of $p < 0.017$.