1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STARTVAC emulsion for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Active substances:
Escherichia coli J5 inactivated > 50 RED_{60}*
Staphylococcus aureus (CP8) strain SP 140 inactivated, expressing slime associated antigenic complex (SAAC) > 50 RED_{80}**
* RED_{60}: Rabbit effective dose in 60% of the animals (serology).
** RED_{80}: Rabbit effective dose in 80% of the animals (serology).

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	
Simeticone	
Water for injections	

Ivory-coloured homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (cows and heifers).

3.2 Indications for use for each target species

For herd immunisation of healthy cows and heifers, in dairy cattle herds with recurring mastitis problems, to reduce the incidence of sub-clinical mastitis and the incidence and the severity of the clinical signs of clinical mastitis caused by *Staphylococcus aureus*, coliforms and coagulase-negative staphylococci.

The full immunisation scheme induces immunity from approximately day 13 after the first injection until approximately day 78 after the third injection.

3.3 Contraindications

None.

3.4 Special warnings

The whole herd should be immunised.

Immunisation has to be considered as one component in a complex mastitis 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, health monitoring) and other management practices.

Vaccinate healthy animals only.

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 (cows and heifers):

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Injection site swelling[1], injection site pain[2] Elevated temperature[3] Anaphylactic-type reaction[4]

[1]Slight to moderate transient local reactions (up to 5 cm^2 on average) may occur after the administration of one dose, which disappears within 1 or 2 weeks at most.
[2]Slight to moderate transient local reactions that spontaneously subsides in a maximum of 4 days.
[3]A mean transient increase in body temperature of about 1 °C, in some cows up to 2 °C, may occur in the first 24 hours after injection.
[4]Such reactions may occur in some sensitive animals which might be life-threatening. Under these circumstances, appropriate and rapid 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 at 45 days before the expected parturition date and 1 month thereafter administer a second dose (at least 10 days before calving). A third dose should be administered 2 months thereafter.

The full immunisation program should be repeated with each gestation.

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

No adverse reactions other than those mentioned in section 3.6 were observed after the administration of a double dose of vaccine.

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 : QI02AB17.

To stimulate active immunity against *Staphylococcus aureus*, coliforms and coagulase-negative staphylococci.

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 stored at 15 ºC to 25 ºC.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I colourless glass vials of 3, 10 and 50 ml.
Polyethylene (PET) vials of 10, 50 and 250 ml.
The vials are closed with a rubber stopper and aluminium cap.

Pack sizes:
Cardboard box with 1 glass vial of 1 dose.
Cardboard box with 10 glass vials of 1 dose.
Cardboard box with 20 glass vials of 1 dose.
Cardboard box with 1 glass vial of 5 doses.
Cardboard box with 10 glass vials of 5 doses.
Cardboard box with 1 glass vial of 25 doses.
Cardboard box with 10 glass vials of 25 doses.
Cardboard box with 1 PET vial of 5 doses.
Cardboard box with 1 PET vial of 25 doses.
Cardboard box with 1 PET vial of 125 doses.

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/2/08/092/001-010

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 11/02/2009

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).