Name of Product

STARTVAC®

Emulsion for injection for cows and heifers

Pharmaceutical form:

Emulsion for injection.

Ivory-coloured homogeneous emulsion.

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

Excipient:

Benzyl alcohol 21 mg

Indications

Target species

Cattle (cows and heifers).

Indications for use

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.

Administration route

Intramuscular use. The vaccinations should be preferably administered on the alternate sides of the neck.

Dosage

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 immunization program should be repeated with each gestation.

Side effects & Contraindications

Adverse reactions

Very rare adverse reactions:

Slight to moderate transient local reactions may occur after the administration of one dose of vaccine. They would mainly be: swelling (up to 5 cm^2 on average), which disappears within 1 or 2 weeks at most. In some cases, there may also be pain at the inoculation site that spontaneously subsides in a maximum of 4 days.

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.

Anaphylactic-type reactions may occur in some sensitive animals which might be life-threatening. Under these circumstances, appropriate and rapid symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

Contraindications

None.

Withdrawal period

Zero days.

Special Precautions

Special precautions for use

Only healthy animals should be immunised.

Special warnings for each target species

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.

Special precautions to be taken by the person administering the veterinary medical 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 medicaments 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 adverse reactions other than those mentioned in section “Adverse reactions” were observed after the administration of a double dose of vaccine.

Incompatibilities

Do not mix with any other vaccine or immunological product.

Special storage precautions for storage

Store and transport refrigerated (+2 to +8 °C) and protected from light. Do not freeze.

Shelf life

18 month from date of manufacturing.

Shelf life after first opening the immediate packaging: 10 hours stored at room temperature (+15 to +25 °C).

Do not use after the expiry date stated on the label.

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

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

Keep out of the reach and sight of children.

Packaging

Pack sizes

- Cardboard box with 1 vial of 1 dose.
- Cardboard box with 10 vials of 1 dose.
- Cardboard box with 20 vials of 1 dose.
- Cardboard box with 1 vial of 5 doses.
- Cardboard box with 10 vials of 5 doses.
- Cardboard box with 1 vial of 25 doses.
- Cardboard box with 10 vials of 25 doses.

Not all pack sizes may be marketed..

Further Information

Immunological properties

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

Pharmacotherapeutic group: Inactivated bacterial vaccines for *bovidae.*

ATCvet code: QI02 AB

Marketing Authorization Numbers, Names and Addresses

Marketing Authorisation Holder

LABORATORIOS HIPRA, S.A.

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Marketing Authorisation Number

EU/2/08/092/001-007

Legal Category

FOR VETERINARY USE ONLY

Date of Preparation or Last Review

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Use medicines responsibly.