# STARTVAC®

## Emulsion for injection for cattle

**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

**NAME OF THE VETERINARY MEDICINAL PRODUCT:**

STARTVAC emulsion for injection for cattle

**STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S):**

One dose (2 ml) contains:
*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).
STARTVAC is an ivory-coloured homogeneous emulsion for injection.

**INDICATION(S):**

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.

**CONTRAINDICATIONS:** None.

**ADVERSE REACTIONS:**

Very rare adverse reactions:
- Slight to moderate transient local reactions may occur after the administration of one dose of vaccine based on post-authorisation pharmacovigilance reporting. 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 ºC, in some cows up to 2 ºC, may occur in the first 24 hours after injection based on post-authorisation pharmacovigilance reporting.
- Anaphylactic-type reactions may occur in some sensitive animals which might be life-threatening based on post-authorisation pharmacovigilance reporting. 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 treated displaying adverse reactions)
- 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 serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

**TARGET SPECIES:** Cattle (cows and heifers).

**DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION:**

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

**ADVICE ON CORRECT ADMINISTRATION:**

Allow the vaccine to reach a temperature of 15 ºC to 25 ºC before administration. Shake before use.

**WITHDRAWAL PERIOD:**

Zero days.

**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 immediate packaging: 10 hours stored 15 ºC to 25 ºC.

**SPECIAL WARNING(S):**

**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 for use in animals**

Vaccinate healthy animals only.

**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)**

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 veterinary medicinal product.

**SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS:**

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

**DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:** June 2023.
Detailed information on this product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

**OTHER INFORMATION: Pack sizes:**

- Cardboard box with 1, 10 and 20 glass vials of 1 dose.
- Cardboard box with 1 and 10 glass vials of 5 doses.
- Cardboard box with 1 and 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.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**UK:** POM-V
To be supplied only on veterinary prescription

**IE:** POM
Prescription Only Medicine

For Animal Treatment Only



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