Vial Labels **December 2013**

STARTVAC
Emulsion for Injection

[1 dose (2mL) ; 5 doses (10mL) ; 25 doses (50mL)]

One dose contains:
E. coli J5 inactivated; *S. aureus* CP8 strain SP 140 inactivated; liquid paraffin, benzyl alcohol.

Withdrawal period:
Zero days

For intramuscular use.

Once opened, use within a 10 hour period, stored at +15 - + 25 °C.

RVM No. A10856

FOR ANIMAL TREATMENT ONLY

Batch:

Exp:

[Hipra contact details]

Leaflet **December 2013**

STARTVAC

Emulsion for injection for cattle

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S):
Escherichia coli (J5) inactivated > 50 RED60*
Staphylococcus aureus (CP8) strain SP 140 inactivated, expressing Slime Associated Antigenic Complex (SAAC) > 50 RED80**
* RED60: Rabbit effective dose in 60 % of the animals (serology).
** RED80: Rabbit effective dose in 80 % of the animals (serology).
Liquid paraffin: 18.2 mg. Benzyl alcohol: 21 mg
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 (equivalent to 130 days post-parturition).

CONTRAINDICATIONS: None.

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 cm2 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.
Animals immunised with an overdose did not show adverse reactions other than those observed after the administration of one dose of vaccine.
If you notice any serious effects or other effects not mentioned in this 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) be deep intramuscular injection in the neck muscles and according to the following schedule:
- First injection at 45 days before the expected parturition date.
- Second injection 35 days thereafter (corresponding to 10 days before the expected parturition date).
- Third injection 62 days after the second injection (equivalent to 52 days post-parturition).
The full immunisation program should be repeated with each gestation.

ADVICE ON CORRECT ADMINISTRATION:
Allow the vaccine to reach a temperature of +15 to + 25 °C before administration. Shake before use.

WITHDRAWAL PERIOD: Zero days.

SPECIAL STORAGE PRECAUTIONS:
Keep out of the reach and sight of children.
Store and transport refrigerated (+2 to +8 °C) and protected from light. Do not freeze.
Do not use after the expiry date stated on the label.
Shelf life after first opening the immediate packaging: 10 hours stored +15 to +25 °C.

SPECIAL WARNING(S):
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. Only healthy animals should be immunised.
Special precautions to be taken by the person administering the veterinary medicinal product to animals.
To the user: This 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 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 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.
Can be used during pregnancy and lactation.
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. Do not mix with any other vaccine or immunological product.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS:
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

OTHER INFORMATION:
Pack sizes:
- Cardboard box with 1 vials of 1 dose.
- Cardboard box with 10 vials of 1 dose.
- Cardboard box with 20 vials of 1 dose.
- Cardboard box with 1 vials of 5 doses.
- Cardboard box with 10 vials of 5 doses.
- Cardboard box with 1 vials of 25 doses.
- Cardboard box with 10 vials of 25 doses.

Not all pack sizes may be marketed.

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