DATA SHEET OR SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTIVAC injectable suspension for bovine.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE ACTIVE SUBSTANCES AND OTHER SUBSTANCES

Each dose (5 ml) contains:

Active substances:

Inactivated Streptococcus agalactiae, strain LO1*:*	*≥1 R.P.*.*
Inactivated Streptococcus dysgalactiae, strain ATCC 43078*:*	*≥1 R.P.*.*
Inactivated Streptococcus uberis, strain LO1*:*	*≥1 R.P.*.*
Inactivated Streptococcus pyogenes, strain LO1*:*	*≥1 R.P.*.*
Inactivated Staphylococcus aureus, strain LO1*:*	*≥1 R.P.**
Inactivated Arcanobacterium pyogenes, strain ATCC 9730*:*	*≥1 R.P.**
Inactivated Escherichia coli, strain Bov-10*:*	*≥1 R.P.*.*
Inactivated Escherichia coli strain Bov-14*:*	*≥1 R.P.**
Inactivated Escherichia coli, strain Bov-15*:*	*≥1 R.P.**
Inactivated Escherichia coli, strain Suis-21*:*	*≥1 R.P.**
Inactivated Escherichia coli, strain J5 ATCC 43745:	≥1 R.P.*.

*R.P.: Relative Potency (ELISA on rabbit serum, relative to a reference vaccine).

Adjuvant:

Aluminium hydroxide (Al^{3+}):	8.5 mg

Excipients:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injectable suspension.

4. CLINICAL PARTICULARS

4.1. Target species

Bovine (heifers and cows)

4.2. Indications of use, specifying the target species

For active immunization against clinical and subclinical mammitis of bovine cattle caused by the following microorganisms: *Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis, Streptococcus pyogenes, Staphylococcus aureus, Arcanobacterium pyogenes and Escherichia coli*. Reduction of clinical signs in clinical mammitis and reduction in

somatic cell counts in subclinical mammitis caused by *Streptococcus agalactiae, Streptococcus uberis* and *Staphylococcus aureus.*

The immunity starts 8-10 days after the application of the second dose.

The duration of the immunity is at least 6 months.

4.3. Contraindications

None.

4.4. Special warnings for each target species

Do not vaccinate weak or sick animals.

4.5. Special precautions for use

Special precautions for use in animals:

Not applicable.

Specific precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label.

4.6. Adverse reactions (frequency and seriousness)

A little oedema may very commonly appear up to 1 cm in diameter for two days, appearing the day after vaccination.

Vaccination, often, may cause an increase in temperature in animals of 1ºC, which can reach slightly above 40ºC for a few hours, and goes into remission in 24 hours.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 for every 10 animals treated displaying adverse reactions)
- Common (more than 1 but less than 10 animals for every 100 animals treated)
- Uncommon (more than 1 but less than 10 animals for every 1,000 animals treated)
- Rare (more than 1 but less than 10 animals for every 10,000 animals treated)
- Very rare (less than 1 animal for every 10,000 animals treated, including isolated cases).

4.7. Use during gestation, lactation or lay

It can be used during pregnancy and lactation.

4.8 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. The decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9. POSOLOGY AND ADMINISTRATION ROUTE

Administration route: Subcutaneous, in the neck or in the back.

Dose: 5 ml.

- Primo vaccination: two inoculations with an interval of 15 days between them in different sites of the neck or the back.

The minimum recommended dose for administering the medicinal product is at 20-22 months age, 2 months before first parturition.
Heifers: Administer 2 months before first parturition.
Cows: Administer at any time independently of the physiological state od the animal.

- Revaccination: 6 monthly.

Shake before use.

Keep the maximum asepsis measures during use.

4.10. Overdosage (symptoms, urgency measures, antidotes), if necessary.

Local or general symptoms different that those indicated in point 4.6 have not been described when administering a double dose of the medicinal product.

4.11. Withdrawal period

Zero days.

5. IMMUNOLOGICAL CHARACTERISTICS

Pharmaceutical group: Inactivated bacterial vaccines for bovine cattle.

Code ATCvet: QI02AB

For the active immunization of bovine cattle against mastitis in bovine cattle associated to infections caused by *Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis, Streptococcus pyogenes, Staphylococcus aureus, Arcanobacterium pyogenes* and *Escherichia coli*.

6. PHARMACEUTICAL DATA

6.1. List of excipients
Sodium chloride.
Aluminium hydroxide.
Water for injections.

6.2. Incompatibilities

In the absence of compatibility studies, this veterinary medicine must not be mixed with other veterinary medicinal products.

6.3. Shelf-life
Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the primary packaging: 10 hours.

6.4. Special precautions for storage
Store and transport refrigerated (2ºC - 8ºC)
Do not freeze.
Protect from light.

6.5. Nature and composition of primary packaging

Coloured glass vials type I (25 ml) and type II (100 ml) with rubber stopper type I and aluminium cap.
Formats:
Cardboard box with 1 amber vial of 25 ml containing 20 ml (4 doses).
Cardboard box with 1 amber vial of 100 ml (20 doses).

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products.

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

7. MARKETING AUTHORIZATION HOLDER

CZ Veterinaria, S.A.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra (Spain)

8. MARKETING AUTHORIZATION NUMBER

2990 ESP

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 February 1969
Date of last renewal: 25 February 2014

10. DATE OF REVISION OF THE TEXT

September 2021.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Dispensing conditions: **To be supplied only under veterinary prescription.**

Administration conditions: **Administration under the control and supervision of the veterinarian.**