SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OCUREV Lyophilisate and solvent for suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 drop – approx. 35 µl) of the reconstituted vaccine contains:

Active substance:
Live attenuated *Brucella melitensis*, strain Rev-1 (smooth phase) …… 1 – 2 x10^9 cfu*

* cfu: colony forming units

Excipient(s):
Patent Blue V (E-131) …… 0.1 mg/ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and goats (replacement).

4.2 Indications for use, specifying the target species

For active immunisation of sheep and goats to reduce infection and clinical signs caused by *Brucella melitensis.*

4.3 Contraindications

Do not vaccinate females in the pregnancy/lactation period (see item 4.7).

4.4 Special warnings for each target species

The vaccine is only used in replacement flocks.
Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Application should be done under strict veterinary control and comply with the established requirements of the legislation in force. The measures to be adopted for the vaccinated animals and their waste materials, in accordance with the legislation in force, as well as other safety measures that official authorities determine should be taken into account.

The risk of vaccinated animals transmitting the vaccine strain to other stock living with them is practically negligible. Therefore, if non vaccinated animals (including cattle) have contact with the vaccine strain from animals vaccinated with this speciality, they could give positive results in the serological tests. To prevent this possibility, it is advisable that vaccination is done, ideally, in an area different from the one used to house the bulk of the herd and that the vaccinated animals are kept segregated during two weeks from vaccination, as during this period the excretion of the vaccine strain can be produced through the body fluids (nasal cavities and conjunctiva).

Special warning: The microorganism is detectable at 15 days after vaccination in some organs. Taking into account that there could be a potential persistence in cranial lymph nodes for longer time, vaccinated animals should not be slaughtered in the period of 3 months after vaccination. Just in case they should be slaughtered, they will be subjected to the procedures applicable to the animals considered positive to Brucellosis, and the official veterinary documents that legislation in force requires will be necessary.

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

The vaccine can be pathogenic for humans. Since this vaccine has been prepared with a live, attenuated microorganism, appropriate measures must be taken to prevent contamination of the handler and other people that collaborate in the process. If accidental contamination during handling of the vaccine were to occur, seek medical advice immediately and show the package insert to the doctor.

It should not be administered by pregnant women.

During the administration of the product, the person or people who carry it out should be protected with glasses, gloves and mask, hold tightly the head of the animal to avoid sudden movements, and perform it in a safe-guard place in order to protect themselves from gusts of wind. The contact of the glove with the mucouses and/or open wounds during and after administration should be avoided.

It should be also taken into account that the period of excretion of the vaccine strain through the body fluids of the vaccinated animals can last until 2 weeks after administration.

Do not smoke, drink nor eat during the administration.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur. This event is very rare. Should this be the case, an appropriate antihistaminic therapy must be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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).

4.7 Use during pregnancy, lactation or lay

Do not use during the whole 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. 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.

4.9 Amounts to be administered and administration route

Dose: 1 drop (approx. 35 µl) per ocular use to sheep and goats from 3 to 6 months of age.

Maintain usual aseptic conditions.

Reconstitute the vaccine with the coloured solvent, wait some minutes and shake gently to prevent foaming. Carefully remove seal and stopper and place the dropper on the vial mouth. Dispense only 1 drop in the eye of the animal. If there is no warranty that the drop has been deposited correctly, the procedure can be repeated in the other eye.

The vaccine should be administered within 6 hours after reconstitution.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

With a ten fold dose it was observed a slight hyperthermia at 4 hours.

4.11 Withdrawal period(s)

30 days (see 4.5).

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live bacterial vaccines for sheep and goats.
ATC vet code: QI04AE/QI03AE.

Rev-1 is an attenuated, smooth strain of *B. melitensis*, streptomycin non-dependent, isolated from streptomycin dependent cells, which was obtained from the virulent strain 6056.

The vaccine organism is streptomycin resistant.

The Rev-1 strain has the following characteristics:

- It stimulates active immunity and induces cell immune response against *Brucella* infections.
- Conjunctival administration induces a weak and short-lasting serological response that avoids the interference with the conventional brucellosis serological tests 4 months after vaccination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<u>Lyophilisate</u>
Tryptone
Sucrose
Thiourea
Ascorbic acid

Sodium glutamate
Highly purified water

Solvent
Sodium chloride
Patent Blue V (E-131)
Highly purified water

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product 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 for 10 and 50 doses vials.
1 year for 25 doses vials.

Shelf-life after reconstitution according to directions: 6 hours.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.
May be transported and stored up to a maximum of 37ºC for a period not longer than 7 days.

6.5 Nature and composition of immediate packaging

The material of the container is as follows:

Lyophilisate
- 11 cc, Type I neutral glass vial (pack sizes of 10, 25 and 50 doses).
- Type I vacuum closing, butyl rubber stopper.
- Aluminium seal.

Solvent
- 3 cc, Type I neutral glass vial containing 0.5 ml (10 doses), 1 ml (25 doses) or 2 ml (50 doses).
- Type I insulin butyl rubber stopper.
- Type insulin aluminium seal.

- Sterile PVC dropper adjustable to the vial.

Pack sizes:
1 cardboard box with 1 vial of 10 doses, 1 vial of 0.5 ml of solvent and one dropper.
1 cardboard box with 1 vial of 25 doses, 1 vial of 1 ml of solvent and one dropper.
1 cardboard box with 1 vial of 50 doses, 1 vial of 2 ml of solvent and one dropper.

Not all pack sizes may be marketed.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CZ Veternaria, S.A.
La Relva s/n – Torneiros
36410 Porriño (Spain)

8. MARKETING AUTHORISATION NUMBER

Spain: 1481 ESP
Portugal: R744DGV
France: FR/V/1723018 6/2017

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 20/11/2002
Date of last renewal:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE>
Not applicable.

Veterinary medicinal product subject to prescription.
Veterinary use.
Administration under control or supervision of a veterinary surgeon.