LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OCUREV
Brucella melitensis
Ocular route

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

Live attenuated *B. melitensis*, strain Rev-1 (smooth phase) ..... 1– 2 x 10^9 cfu
Patent Blue V (E-131)..... 0.01 %

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension

4. PACKAGE SIZE

10 doses
25 doses
50 doses

5. TARGET SPECIES

Sheep and goats (replacement)

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer 1 drop (1 dose) in the eye of the animal
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: 30 days

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer to females in the pregnancy/lactation period

Accidental administration or contact with the mucosa is dangerous – see package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, the vaccine should be used within 6 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport at 2-8ºC.
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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused product or waste materials should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
Veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CZ Veterinaria, S.A.
36410 Porriño (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FREEZE-DRIED

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OCUREV

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live attenuated *Brucella melitensis*, Rev-1 (smooth phase) …… 1-2 x 10^9 cfu

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 doses
25 doses
50 doses

4. ROUTE(S) OF ADMINISTRATION

Ocular route

5. WITHDRAWAL PERIOD

30 days

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted, the vaccine should be used within 6 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SOLVENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OCUREV DILUENT

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Patent Blue V (E-131) …… 0.01%

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.5 ml
1 ml
2 ml

4. ROUTE(S) OF ADMINISTRATION

Ocular route

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

CZ Veterinaria, S.A.
36410 Porriño (Spain)

PACKAGE LEAFLET

OCUREV

Lyophilisate and solvent for suspension.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OCUREV

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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) …… 0.01 %

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not vaccinate females in the pregnancy/lactation period.

6. ADVERSE REACTIONS

Hypersensitivity reactions may occur. Should this be the case, an appropriate antihistaminic therapy must be administered.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep and goats (replacement)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose: 1 drop (approx. 35 µl) per ocular route 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

30 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport refrigerated (2 °C – 8 °C)
Protect from light
Do not freeze

Do not use after the expiry date which is stated on the label.
Shelf-life after dilution or reconstitution according to directions: 6 hours
May be transported and stored up to a maximum of 37ºC for a period not longer than 7 days.

12. SPECIAL WARNING(S)

Special warnings for each target species.

The vaccine is only used in replacement flocks.

Special precautions for use in animals.

Vaccinate only healthy and parasite free animals.

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.

Eliminate in a safe manner all material coming from the vaccination at the end of the working day.

Do not smoke, drink nor eat during the administration.

Use during pregnancy, lactation or lay.

Do not administer to females in the pregnancy/lactation period.

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

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

Incompatibilities

Do not mix with any other vaccine/immunological product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused product or waste materials should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2017

15. OTHER INFORMATION

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, the principal defence mechanism 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.

Pack sizes:

Outer box with 1 vial of 10 doses and 1 vial of 0.5 ml of solvent and sterile dropper.
Outer box with 1 vial of 25 doses and 1 vial of 1 ml of solvent and sterile dropper.
Outer box with 1 vial of 50 doses and 1 vial of 2 ml of solvent and sterile dropper.

Not all pack sizes may be marketed.

Veterinary prescription
Veterinary use
Administration under control or supervision of a veterinary surgeon.