

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OCUREV Lyophilisate and solvent for suspension

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 10⁹ cfu
Patent Blue V (E-131)..... 0.1 mg/ml

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

Ocular use. 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 2-8°C

Protect from light

Do not freeze

May be transported and stored up to a maximum of 37°C for a period not longer than 7 days

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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

To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CZ Veterinaria, S.A.

La Relva s/n – Torneiros

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 Lyophilisate and solvent for suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live attenuated *Brucella melitensis*, Rev-1 (smooth phase) 1-2 x 10⁹ cfu

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

10 doses

25 doses

50 doses

4. ROUTE(S) OF ADMINISTRATION

Ocular use

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
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DILUENT FOR OCUREV Lyophilisate and solvent for suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Patent Blue V (E-131) 0.1 mg/ml

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

0.5 ml

1 ml

2 ml

4. ROUTE(S) OF ADMINISTRATION

Ocular use

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