

## **A. LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Folding box}

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Catobevit 100 mg/ml + 0.05 mg/ml solution for injection for cattle (DE)

Ralcam 100 mg/ml + 0.05 mg/ml solution for injection for cattle (CZ)

Butafosfan, cyanocobalamin

### 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

**Active substances:**

Butafosfan: 100.00 mg

Cyanocobalamin (vitamine B12): 0.05 mg

### 3. PHARMACEUTICAL FORM

Solution for injection.

### 4. PACKAGE SIZE

100 ml

250 ml

### 5. TARGET SPECIES

Cattle



### 6. INDICATION(S)

### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Route of administration: IV

Dose:

Cattle: 5 mg of butafosfan and 2.5 µg of cyanocobalamin per kg bodyweight (bw) corresponding to 5 ml / 100 kg bw daily with an 24 hour interval for three consecutive days.

### 8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Meat and offal: zero days

Milk: zero hours

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Shelf life after first opening the container: 28 days

Once opened use by...

**11. SPECIAL STORAGE CONDITIONS**

Store the bottle in the outer box in order to protect from light.

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

Dispose of waste material 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**

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

{Label}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Catobevit 100 mg/ml + 0.05 mg/ml solution for injection for cattle (DE)

Ralcam 100 mg/ml + 0.05 mg/ml solution for injection for cattle (CZ)

Butafosfan, cyanocobalamin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

Butafosfan: 100.00 mg

Cyanocobalamin (vitamine B12): 0.05 mg

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

100 ml

250 ml

**5. TARGET SPECIES**

Cattle



**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

IV

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period(s):

Meat and offal: zero days

Milk: zero hours

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

<b>10. EXPIRY DATE</b>
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EXP {month/year}

Shelf life after first opening the container: 28 days

Once opened use by...

<b>11. SPECIAL STORAGE CONDITIONS</b>
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Store the bottle in the outer box in order to protect from light.

<b>12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY</b>
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<b>13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE</b>
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For animal treatment only. To be supplied only on veterinary prescription.

<b>14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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<b>15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b>
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KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

<b>16. MARKETING AUTHORISATION NUMBER(S)</b>
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<b>17. MANUFACTURER’S BATCH NUMBER</b>
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Lot {number}

