B. PACKAGE LEAFLET

PACKAGE LEAFLET:
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)

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

Marketing authorisation holder:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

2. 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

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

Each ml contains:

Active substances:
Butafosfan: 100.00 mg
Cyanocobalamin (vitamine B12): 0.05 mg

Excipients:
Phenol: 4.00 mg

Pink to reddish pink solution.

4. INDICATION(S)

For the supportive treatment of secondary ketosis (e. g. in abomasal displacement).

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

For intravenous use.

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.

9. ADVICE ON CORRECT ADMINISTRATION

The cap may be safely punctured up to 25 times. If more than 25 broachings are required, use of a draw off needle is recommended.

10. WITHDRAWAL PERIOD(S)

Meat and offal: zero days
Milk: zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Store the bottle in the outer box in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to any of the ingredients should avoid contact with the product. The product might be mildly irritating to the skin or the eye. Dermal and ocular exposure should therefore be avoided. In case of accidental dermal or ocular exposure rinse the skin and/or the eye with water.

Pregnancy and lactation:
No negative effects on the use of the product during pregnancy or lactation have been reported. Can be used during pregnancy and lactation.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

100 ml amber glass bottle type II with bromobutyl rubber stopper and aluminium cap with a flip-off seal.
250 ml amber glass bottle type I with bromobutyl rubber stopper and aluminium cap with a flip-off seal.

Pack sizes:
Box with 1 bottle of 100 ml
Box with 1 bottle of 250 ml

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.