

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Folding box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vey Tosal 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (AT/ BE/ BG/ CY/ CZ/ DE/ ES/ FR/ GR/ HR/ HU/ IE/ IT/ LT/ LV/ LU/ MT/ NL/ PL/ PT/ RO/ SI/ SK/ UK))

Veytosol Vet 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (NO/DK/ FI/ IS)

Phoscobal vet 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (SE)

Vey Tosal (EE)

Butafosfan / cyanocobalamin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substances:

Butafosfan: 100.00 mg

Cyanocobalamin (vitamin B12): 0.05 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Cattle, horses, dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Route of administration:

Cattle, horses: IV

Dogs and cats: IV, IM, SC

Dose

Cattle and horses: 0.02 - 0.05 ml product/kg b.w.

Calves and foals: 0.033 - 0.056 ml product/kg b.w.

Dogs: 0.025-0.25 ml product/kg b.w.

Cats: 0.1-0.5 ml product/kg b.w.

8. WITHDRAWAL PERIOD (S)

Withdrawal periods:

Cattle, horses:

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}

Once broached use within 28 days.

Once opened use by.....

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton 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

Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vey Tosal 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats
(AT/ BE/ BG/ CY/ CZ/ DE/ ES/ FR/ GR/ HR/ HU/ IE/ IT/ LT/ LV/ LU/ MT/ NL/ PL/ PT/ RO/ SI/
SK/ UK))

Veytosal Vet 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats
(NO/DK/ FI/ IS)

Phoscobal vet 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (SE)

Vey Tosal (EE)

Butafosfan / cyanocobalamin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substances:

Butafosfan: 100.00 mg

Cyanocobalamin (vitamin B12): 0.05 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Cattle, horses, dogs and cats

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

Read the package leaflet before use.

Cattle, horses: IV

Dogs and cats: IV, IM, SC

8. WITHDRAWAL PERIOD (S)

Withdrawal periods:

Cattle, horses:

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}

Once broached use within 28 days

Once opened use by.....

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**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”**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
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16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

