

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**Cardboard box****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vey Tosal 100 mg/ml + 0.05 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Butafosfan 100.00 mg

Cyanocobalamin (vitamin B₁₂) 0.05 mg**3. PACKAGE SIZE**

100 ml

250 ml

4. TARGET SPECIES

Cattle, horses, dogs.

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**Cattle, horses:

Intravenous use.

Dogs:

Intravenous, intramuscular and subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle and horses:

Meat and offal: Zero days.

Milk: Zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: 28 days.

Once broached, use by ____

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”
--

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”
--

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH

14. MARKETING AUTHORISATION NUMBERS
--

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial (100 ml, 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vey Tosal 100 mg/ml + 0.05 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Butafosfan 100.00 mg

Cyanocobalamin (vitamin B₁₂) 0.05 mg

3. TARGET SPECIES

Cattle, horses and dogs:

4. ROUTES OF ADMINISTRATION

Cattle, horses:

Intravenous use.

Dogs:

Intravenous, intramuscular and subcutaneous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle and horses:

Meat and offal: Zero days.

Milk: Zero hours.

6. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: 28 days.

Once broached, use by ____

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER
--

Veyx-Pharma GmbH

9. BATCH NUMBER

Lot {number}