ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Folding box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Catophos 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats

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,

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

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 20916/3000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Catophos 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats

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,

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

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 20916/3000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET:
Catophos 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats

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

Marketing authorisation holder and manufacturer responsible for batch release:

CP- Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Catophos 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats

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

Each ml contains

Active substances:

Butafosfan:	100.00 mg
Cyanocobalamin (vitamin B12):	0.05 mg

Excipient:

Benzyl alcohol (E 1519)	20.00 mg

Clear, pink solution.

4. INDICATION(S)

As supportive treatment of metabolic or reproductive disorders, when supplementation of phosphorous and cyanocobalamin is needed.
In case of peri-parturient metabolic disorders, tetany and paresis (milk fever), the product should be administered in addition to magnesium and calcium, respectively.
Supporting muscle function in the presence of deficiencies of phosphorous and/or cyanocobalamin.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

In cats, following subcutaneous injection in the interscapular region, reactions at injection site (swelling, oedema, erythema and induration) can be observed.

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, horses, dogs and cats.

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

Cattle, horses: for intravenous use
Dogs and cats: for intravenous, intramuscular and subcutaneous use

Animal species / sub-category	Butafosfan (mg/kg)	Vitamin B_{12} (µg/kg)	Product (ml/kg)	Route of administration
Cattle	2.0 - 5.0	1.0 - 2.5	0.02 - 0.05	IV
Calves	3.3 - 5.6	1.65 - 2.8	0.033 - 0.056	IV
Horses	2.0 - 5.0	1.0 - 2.5	0.02 - 0.05	IV
Foals	3.3 - 5.6	1.65 - 2.8	0.033 - 0.056	IV
Dogs	2.5 - 25	1.25 - 12.5	0.025-0.25	IV, IM, SC
Cats	10 - 50	5.0 - 25	0.1-0.5	IV, IM, SC

Repeat once daily, if necessary.

9. ADVICE ON CORRECT ADMINISTRATION

The cap may be safely punctured up to 40 times. If more than 40 broachings are required, use of a draw off needle is recommended.
It is recommended to use 100 ml packaging for treatment of dogs and cats.

10. WITHDRAWAL PERIOD(S)

Cattle, horses:
Meat and offal: zero days
Milk: zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the vial after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
It is recommended to determine the cause(s) of the metabolic or reproductive disorders to define the most appropriate measures of prevention and treatment and the need for a therapy with supplemental phosphorus and vitamin B_{12}.
Due to a deficiency in glucuronidating metabolic pathways in cats, which are involved in benzyl alcohol metabolism, this veterinary medicinal product should be used with caution and the recommended dose should be strictly observed in this species.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product contains benzyl alcohol which may cause hypersensitivity (allergic) reactions. People with known hypersensitivity to benzyl alcohol should avoid contact with the veterinary medicinal product.
This product may cause irritation of skin, eyes, and mucous membranes. Such contact with the product should be avoided. In case of accidental exposure, rinse the affected area thoroughly with water.
Do not eat, drink or smoke while handling the product.
Wash hands after use.

Pregnancy and Lactation:
The safety of the veterinary medicinal product has not been established in pregnant and lactating cows, mares, bitches and queens. However, its use during pregnancy and lactation in those species should not pose any particular problem.

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

Amber glass vial type II with bromobutyl rubber stopper and aluminium cap.

Pack sizes:
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 ml

Not all pack sizes may be marketed.

België/Belgique/Belgien
{{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }
BE-0000 {Localité/Stad/Stadt}>
Tél/Tel: + {N° de téléphone/Telefoonnummer/ Telefonnummer}
<{E-mail}>

Република България
{Наименование}
<{Адрес}
BG {Град} {Пощенски код}>
Тел: + 359 {Телефонен номер}
<{E-mail}>

Česká republika
□Název□
<□Adresa
□ CZ
□město□>
Tel: +□telefonní číslo□
<{E-mail}>

Danmark
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Tel: + {Telefonnummer}
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Lietuva
{pavadinimas}
<{adresas}
LT {pašto indeksas}
{miestas}> Tel: +370{telefono numeris}
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Luxembourg/Luxemburg
{Nom}
<{Adresse}
L-0000 {Localité/Stadt}>
Tél/Tel: + {N° de téléphone/Telefonnummer}
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Magyarország
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HU-0000 {Város}>
Tel.: + {Telefonszám}
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France
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Hrvatska
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Dublin}> Tel: + {Telephone
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Italia
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IT-00000 {Località}>
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Κύπρος
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Latvija
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Sverige
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SE-000 00 {Stad}>
Tel: + {Telefonnummer}
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United Kingdom (Northern Ireland)
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<{Address}
{Town} {Postal code} –
UK> Tel: + {Telephone number}
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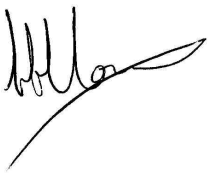

Approved 11 May 2024