ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosacthen 0.25 mg/ml solution for injection for dogs
Tetracosactide

2. STATEMENT OF ACTIVE SUBSTANCES

Tetracosactide 0.25 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM or IV
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

This product may cause hypersensitivity reactions and/or can have adverse effects in pregnant women. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

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

Disposal: read package leaflet.

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

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4099

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosacthen 0.25 mg/ml solution for injection
Tetracosactide

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Tetracosactide 0.25 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

IV or IM

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Cosacthen 0.25 mg/ml solution for injection for dogs

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

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Manufacturer responsible for batch release:
Dales Pharmaceuticals Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire BD23 2RW United Kingdom

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosacthen 0.25 mg/ml solution for injection for dogs
Tetracosactide

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

Active substance: Tetracosactide 0.25 mg/ml
(equivalent to 0.28 mg tetracosactide hexaacetate)
Clear, colourless solution.

4. INDICATION(S)

For the evaluation of adrenocortical function in dogs.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Vomiting was observed commonly during clinical studies.
Application site bruising (IM route of administration), injection site haematoma (IV route of administration), depression, diarrhoea, lameness, and nervousness occurred uncommonly during clinical studies.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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

Dogs

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

Administer 5 µg/kg (0.02 mL/kg) by intravenous or intramuscular injection, with the purpose of performing the ACTH stimulation test. Take the first blood sample immediately prior to administering the product, and take the second blood sample between 60 and 90 minutes after administration of the product, to assess the cortisol response.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

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 label and carton. The expiry date refers to the last day of that month.

Once broached use immediately. Any product remaining after first use must be discarded.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

The safety of the product has not been established in dogs under 5 months of age, or weighing less than 4.5 kg.
The efficacy and safety of the product has not been established in dogs with diabetes mellitus or hypothyroidism.
Use only according to the benefit /risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Tetracosactide can cause hypersensitivity in people, particularly those with existing allergic disorders, such as asthma. People with such allergic disorders, or a known hypersensitivity to tetracosactide, ACTH or any of the excipients, should avoid contact with the product. If you develop clinical symptoms following exposure, such as skin reactions, nausea, vomiting, oedema and dizziness, or any signs of anaphylactic shock, you should seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after use.

Tetracosactide has not been tested in reproductive or developmental toxicity studies, but the pharmacological effects on the hypothalamic-pituitary-adrenal axis can have adverse effects in pregnancy. Therefore, the veterinary medicinal product should not be administered by pregnant or breastfeeding women. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy and lactation:

Do not use during pregnancy. Tetracosactide affects the hypothalamic-pituitary-adrenal (HPA) axis, which can be detrimental to the foetus.
The safety of the veterinary medicinal product has not been established during lactation. The use of the product is not recommended during lactation.

Interaction with other medicinal products and other forms of interaction:

Before performing an ACTH stimulation test, ensure that a sufficient wash-out period has elapsed since the administration of any medicinal product which may either cross-react with the cortisol assay, or have an effect on the hypothalamic-pituitary-adrenal (HPA) axis.

Overdose (symptoms, emergency procedures, antidotes):

In a tolerance study where eight dogs were administered 280 µg/kg tetracosactide (56 times the recommended dose) intravenously once weekly for three weeks, hypersalivation occurred on eight of 24 dosing occasions (33% incidence). In the same study, injected mucous membranes, inguinal erythema, facial oedema, and tachycardia, characteristic of a hypersensitivity reaction was observed in one dog following administration of the third dose.

Incompatibilities:

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

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

September 2020

15. OTHER INFORMATION

Pack size: 1 ml vial per box.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 17 September 2020