

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosacthen 0.25 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tetracosactide 0.25 mg
(equivalent to 0.28 mg tetracosactide hexaacetate)

3. PACKAGE SIZE

1 ml

4. TARGET SPECIES

Dogs.



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

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

This product may cause hypersensitivity reactions and/or can have adverse effects in pregnant women. 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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/3029

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {VIAL LABEL}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosacthen



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Tetracosactide 0.25 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cosacthen 0.25 mg/ml solution for injection for dogs

2. Composition

Each ml contains:

Active substance:

Tetracosactide 0.25 mg/ml
(equivalent to 0.28 mg tetracosactide hexaacetate)

Clear, colourless solution.

3. Target species

Dogs.



4. Indications for use

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. Special warnings

Special precautions for safe use in the target species:

The safety of the veterinary medicinal product has not been established in dogs under 5 months of age or weighing less than 4.5 kg.

The safety of the veterinary medicinal 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 veterinary medicinal 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 women.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

Tetracosactide affects the hypothalamic-pituitary-adrenal (HPA) axis, which can be detrimental to the foetus.

Do not use (during the whole or part of the pregnancy).

The safety of the veterinary medicinal product has not been established during lactation.

The use 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:

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.

Major incompatibilities:

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

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Vomiting
Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site bruising ^a , Injection site haematoma ^b Depression Diarrhoea Lameness Nervousness

^aAfter intramuscular administration.

^bAfter intravenous administration.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intravenous or intramuscular use.

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 veterinary medicinal product, and take the second blood sample between 60 and 90 minutes after administration of the veterinary medicinal product, to assess the cortisol response.

To ensure a correct dosage, body weight should be determined as accurately as possible.

9. Advice on correct administration

10. Withdrawal periods

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 after Exp. 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 precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/3029

Pack size: 1 ml vial per box.

15. 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.

16. Contact details

Marketing authorisation holder:

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

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

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

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

17. Other information

POM-V

Gavin Hall
Approved: 25 April 2025