Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cosacthen 0.25 mg/ml solution for injection for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:
Tetracosactide 0.25 mg
(equivalent to 0.28 mg tetracosactide hexaacetate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For the evaluation of adrenocortical function in dogs.

4.3 Contraindications

Do not use in pregnant animals, see section 4.7.
Do not use in cases of hypersensitivity to the active substances, or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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

4.6 Adverse reactions (frequency and seriousness)

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)

4.7 Use during pregnancy, lactation or lay

Pregnancy
Do not use during pregnancy. Tetracosactide affects the hypothalamic-pituitary-adrenal (HPA) axis, which can be detrimental to the foetus.

Lactation
The safety of the veterinary medicinal product has not been established during lactation. The use of the product is not recommended during lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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.
The HPA axis may be affected by medicinal products which either interact with glucocorticoid receptors, or which affect the pathways involved in the synthesis and release of cortisol from the adrenal gland.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anterior pituitary lobe hormones and analogues.
ATC vet code: QH01AA02.

5.1 Pharmacodynamic properties

Tetracosactide is a synthetic polypeptide, which consists of the first 24 amino acids of adrenocorticotropic hormone (ACTH). The administration of tetracosactide results in cortisol concentrations that are significantly elevated compared to baseline values. Administration of tetracosactide at a dose of 5 µg/kg, either by intravenous or intramuscular administration, leads to a

maximum concentration of cortisol at 60 to 90 minutes after administration. Doses lower than 5 µg/kg result in a shorter duration of maximal cortisol secretion than a dose of 5 µg/kg. Doses higher than 5 µg/kg do not cause higher peak cortisol concentrations.

5.2 Pharmacokinetic particulars

Compared to intramuscular administration, intravenous administration of tetracosactide results in a higher maximum plasma concentration (Cmax) of immunoreactive (IR)-ACTH, a measurement which includes both endogenous ACTH and tetracosactide. By either route of administration, the time of peak concentration (Tmax) of IR-ACTH occurs at or before 30 minutes following administration. Peptidases rapidly break tetracosactide down into smaller peptides, with a return to baseline IR-ACTH concentrations attained by 120 minutes post-dosing.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetic acid, glacial
Sodium acetate trihydrate
Sodium chloride
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
For single use only; any product remaining after first use must be discarded.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Type I clear glass vial with a coated rubber stopper and aluminium seal packed in a cardboard box.
Pack size: 1 ml vial per box.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA22622/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 February 2020

10 DATE OF REVISION OF THE TEXT