Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Canaural ear drops, suspension for dogs and cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of suspension contains:

Active Substances:

Diethanolamine fusidate	5	mg
Framycetin sulphate	5	mg
Nystatin	100,000	IU
Prednisolone	2.5	mg

Excipients:

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Ear drops, suspension.
A yellow oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

For the treatment of otitis externa including the ear mite *Otodectes cynotis* infestation in the dog and cat.

4.3 Contraindications

Do not use in animals with a perforated ear drum.
Do not use concomitantly with products known to be ototoxic.
Do not use in animals with known hypersensitivity to the active substances or the excipient.

4.4 Special warnings for each target species

For external use only.
To be used under veterinary supervision.

4.5 Special precautions for use

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Special precautions for use in animals
Following recovery the ears should be checked at regular intervals for any sign of re-infection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid contact with the product.
If the product comes into contact with the eyes, rinse immediately with plenty of water and seek medical advice.
People with known hypersensitivity to any of the active substances or the excipient in the product should avoid contact with the veterinary medicinal product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

On very rare occasions and primarily in geriatric animals, use of auricular preparations may be associated with hearing impairment which may be either transient or prolonged.
Allergy or hypersensitivity reactions to the active substances or the excipient might occur.
Anti-inflammatory corticosteroids such as prednisolone are known to exert a wide range of side effects. Dosage in medium to long term use should therefore generally be kept to the minimum.
During therapy effective doses suppress the hypothalamo-pituitreal adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency can arise and this may render the animal unable to deal adequately with stressful situations.
Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to, or exacerbate existing infections.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and/or lactation.
The use is not recommended during pregnancy and/or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Where appropriate, prior to administration, the ear canal and the surrounding area should be cleaned mechanically or by irrigation taking care to avoid further damage to the skin. Any excess exudate, hair or debris should be carefully removed prior to the application of the ear drops. Animal owners should only do this on the direction of the prescribing veterinary surgeon.
Shake the bottle before using.
Instill 5 - 10 drops into the ear according to the size of the animal and ear canal twice daily.
Without allowing the animal to shake its head, very gently massage the ear canal after administration holding the pinna in an upright position to ensure penetration of the drops into the ear.
Where ear mite infection is present, consideration should be given to treating both ears, even if the infection is apparent only in one. Treatment should continue for at least 3 weeks to ensure that successive generations of ear mites have been killed. Animals in contact should also be treated.
Where treatment is for a period longer than 7 days regular clinical re-evaluation should be carried out. Where Gram-negative infections are involved, the use of the veterinary medicinal product should be based on bacterial sensitivity testing. In cases where the treatment period is prolonged, *in vitro* sensitivity should be re-evaluated.

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

None known.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Otologicals containing corticosteroids and antiinfectives in combination.
ATCvet code: QS02CA01

5.1 Pharmacodynamic properties

The veterinary medicinal product is effective against the micro-organisms commonly associated with otitis externa, including the ear mite, *Otodectes cynotis*, and is specifically formulated for the treatment of otitis externa in the dog and cat.
Fusidic acid (present in the veterinary medicinal product as the diethanolamine salt) is an antibiotic which is highly active against *Staphylococci*, the most commonly found bacterial pathogen in otitis externa in the dog and cat. Fusidic acid has skin penetrating properties which enhance its antibacterial properties.
Framycetin sulphate is a broad spectrum antibiotic which has been incorporated for its activity against Gram-negative organisms associated with otitis externa, in particular *Pseudomonas* spp. and *Proteus* spp..
Nystatin is highly active against yeasts. The yeast, *Malassezia pachydermatis*, is associated with otitis externa in the dog and cat either by itself or with other organisms.
Prednisolone is incorporated for its anti-inflammatory activity.
All four active ingredients are suspended in oil. A bland oil is used which softens and dissolves ceruminous material and readily penetrates the ear canal. Additionally, the oil used does not mat the hair around the ear, which would prove objectionable to both animal and owner.
Clinical trials have demonstrated that the veterinary medicinal product is effective in the treatment of the ear mite, *Otodectes cynotis* in the dog and cat. The mode of action is uncertain as none of the components of the veterinary medicinal product have recognised acaricidal activity

5.2 Pharmacokinetic properties

Fusidic acid and Framycetin are not absorbed into the systemic circulation when used topically. In contrast, prednisolone can in some cases be absorbed when used topically.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sesame oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 3 months.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from direct sunlight.
Keep the bottle in the outer carton.

6.5 Nature and composition of immediate packaging

High density polyethylene squeeze dropper bottles, supplied in pack sizes of 1x15ml, 10x15ml 1x25ml, and 1x100ml. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Dechra Veterinary Products A/S
Mekuvej 9
7171 – Uldum
Denmark

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10803/003/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

October 2012