ANNEX I

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 suspension contains:
Active substances:

Diethanolamine fusidate	5.0 mg
Framycetin sulphate	5.0 mg
Nystatin	100,000 IU
Prednisolone	2.5 mg

Excipient:
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*, in the dog and cat.

4.3 Contraindications

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

4.4 Special warnings

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 signs of re-infection.

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

- Avoid contact with the product.
- Wash hands after use.
- If the product comes into contact with the eyes, rinse immediately with plenty of water.
- People with known hypersensitivity to any of the active substances or the excipient in the product should avoid contact with the veterinary medicinal product.

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 can 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 hypothalamic-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.

Pregnancy and 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 well before use.

Instil 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 infection is apparent in only one. Treatment should continue for at least 3 weeks to ensure that successive generations of ear mites are killed. Animals that are 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

Not applicable.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Otologicals containing corticosteroids and antiinfectives in combination.
ATCvet code: QS 02 CA 01

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 are specifically formulated for the treatment of otitis externa in the dog and cat.

Diethanolamine fusidate
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 enhances its antibacterial properties.

Framycetin sulphate
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
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
Prednisolone is incorporated for its anti-inflammatory and anti-pruritic 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 matt 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 in the veterinary medicinal product have recognised acaricidal activity.

5.2 Pharmacokinetic particulars

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.

5.3 Environmental properties

Not relevant.

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.

6.5 Nature and composition of immediate packaging

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

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

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
DK-7171 Uldum
DENMARK

8. MARKETING AUTHORISATION NUMBER(S)

Vm 24883/4004

9. DATE OF FIRST AUTHORISATION

Date: 24.09.1974

10. DATE OF REVISION OF THE TEXT

Date: September 2012