SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OSURNIA ear gel for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (1.2 g) contains:

Active substances:

Terbinafine:	10 mg
Florfenicol:	10 mg
Betamethasone acetate:	1 mg
equivalent to Betamethasone base	0.9 mg

Excipient:

Butylhydroxytoluene (E321):	1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear gel.
Off-white to slightly yellow translucent gel.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment of acute otitis externa and acute exacerbation of recurrent otitis externa associated with *Staphylococcus pseudintermedius* and *Malassezia pachydermatis*.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances, to other corticosteroids or to any of the excipients.
Do not use if the eardrum is perforated.
Do not use in dogs with generalised demodicosis.
Do not use in pregnant or breeding animals (see section 4.7).

4.4. Special warnings for each target species

Clean the ears before the initial treatment is applied. Ear cleaning should not be repeated until 21 days after the second administration. In clinical trials, saline only was used for ear cleaning.

Transient wetness of the inner and outer pinna can be observed. This observation is attributed to presence of product and is not of clinical concern. Bacterial and fungal otitis is often secondary to other conditions. Appropriate diagnosis should be used and therapy of causative conditions should be investigated before antimicrobial treatment is considered.

In animals with a history of chronic or recurrent otitis externa, efficacy of the product may be affected if the underlying causes of the condition such as allergy or anatomical conformation of the ear are not addressed.

4.5 Special precautions for use

Special precautions for use in animals

If hypersensitivity to any of the components occurs, the ear should be thoroughly washed.

The safety of the product has not been established in dogs less than 2 months of age or weighing less than 1.4 kg.
Whenever possible the use of the veterinary medicinal product should be based on identification of infecting organisms and susceptibility testing.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol and fungi resistant to terbinafine and may decrease the effectiveness of treatment with other antibiotics and antifungal agents.
In case of parasitic otitis, an appropriate acaricidal treatment should be implemented.
Before the veterinary medicinal product is applied, the external auditory canal must be examined thoroughly to ensure that the ear drum is not perforated.
Prolonged and intensive use of topical corticosteroids preparation is known to trigger systemic effects, including suppression of adrenal function (see section 4.10).
Decreased cortisol levels were observed after product instillation in tolerance studies (before and after ACTH stimulation), indicating that betamethasone is absorbed and enters the systemic circulation. The finding was not correlated with pathological or clinical signs and was reversible.
Additional corticosteroid treatments should be avoided.
Use with precaution in dogs with suspected or confirmed endocrine disorder (i.e. diabetes mellitus; hypo- or hyper-thyroid disease, etc.).

The veterinary medicinal product may be irritating to eyes. Avoid accidental contact to the dog's eyes. If accidental ocular exposure does occur, the eyes should be flushed thoroughly with water for 10 to 15 minutes. If clinical signs develop, seek veterinary advice.
In very rare cases, eye disorders such as keratoconjunctivitis sicca and corneal ulcers have been reported in treated dogs, in absence of eye contact with the product. Although a causal relationship with the veterinary medicinal product was not definitivelv established, owners should be recommended to monitor ocular signs

(such as squinting, redness and discharge) in the hours and days following the product application, and to promptly consult a veterinarian in case such signs appear.

The safety and efficacy of the veterinary medicinal product in cats has not been evaluated. Post-marketing surveillance shows that the use of the product in cats can be associated with neurological signs (including Horner's syndrome with protrusion of membrane nictitans, miosis, anisocoria, and internal ear disorders with ataxia and head tilt) and systemic signs (anorexia and lethargy). The use of the veterinary medicinal product in cats should therefore be avoided.

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

The veterinary medicinal product may be irritating to eyes. Accidental eye exposure may occur when the dog shakes its head during or just after administration. To avoid this risk for the owners, it is recommended that this veterinary product is administered only by veterinarians or under their close supervision. Appropriate measures (e.g. wearing safety glasses during administration, massaging the ear canal well after administration to ensure even distribution of product, restraining the dog after administration) are needed to avoid exposure to the eyes. In case of accidental ocular exposure, flush the eyes thoroughly with water for 10 to 15 minutes. If symptoms develop, seek medical advice and show the package leaflet or the label to the physician.

In case of accidental skin contact, wash exposed skin thoroughly with water.
In case of accidental ingestion by humans, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Deafness or impaired hearing, usually temporary, have been reported after use in very rare cases in dogs, mainly in elderly animals, in post authorisation experience.
Application site reactions (i.e. erythema, pain, pruritus, oedema and ulcer) have been reported in very rare cases, in post authorisation experience.
Hypersensitivity reactions including facial oedema, urticaria and shock have been reported in very rare cases, in post authorisation experience.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

Betamethasone is known to be teratogenic in laboratory species. The safety of the veterinary medicinal product has not been established in pregnant and lactating bitches. Do not use during pregnancy and lactation (see section 4.3).

Fertility
Do not use in breeding animals (see section 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

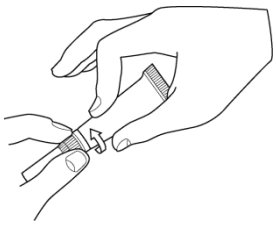
Compatibility with ear cleaners, other than saline, has not been demonstrated.

4.9 Amounts to be administered and administration route

Auricular use.
Administer one tube per infected ear. Repeat the administration after 7 days.
The maximum clinical response may not be seen until 21 days after the second administration.

Instructions for proper use:
It is recommended to clean and dry the external ear canal before the first administration of the product. It is recommended not to repeat ear cleaning until 21 days after the second administration of the product. If treatment with this product is discontinued, the ear canals should be cleaned before treatment with an alternative product is initiated.

1. Open the tube by twisting the soft tip.



2. Introduce this flexible soft tip into the ear canal.

3. Apply the product into the ear canal by pressing it between two fingers.

4. After application, the base of the ear may be massaged briefly and gently to facilitate even distribution of the veterinary medicinal product into the ear canal.

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

Auricular administration of five times the recommended dose, one week apart, for 5 consecutive weeks (a total six administrations of 5 tubes per ear or 10 tubes per dog) to mixed breed dogs weighing 10 to 14 kg resulted in clinical signs of wetness of the inner and outer pinna (attributed to presence of the product). There were no clinical signs associated with unilateral vesicle formation within the epithelium of the tympanic membrane (also observed after six administrations, one week apart, of 1 tube per ear or 2 tubes per dog), unilateral mucosal ulceration in the lining of the middle ear cavity, or decrease in serum cortisol response below normal reference range in ACTH stimulation testing. The decreased adrenal and thymus weights accompanied by atrophy of the adrenal cortex and lymphoid depletion of the thymus correlated with the decreased cortisol levels, and were consistent with the pharmacologic effects of betamethasone. These findings are considered reversible. Reversibility of the epithelial tympanic membrane blistering is also likely through epithelial migration, a natural self-cleaning and self–repair mechanism for the tympanic membrane and ear canal. Additionally, dogs showed slightly elevated red

blood cell count, hematocrit, total protein, albumin and alanine aminotransferase. These findings were not associated with clinical signs.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Otologicals – Corticosteroids and anti-infectives in combination.
ATC-vet code: QS02CA90.

5.1 Pharmacodynamic properties

The veterinary medicinal product is a fixed combination of three active substances (corticosteroid,
antifungal and antibiotic):
Betamethasone acetate belongs to the diesters class of the glucocorticosteroids with a potent intrinsic glucocorticoid activity which relieves both inflammation and pruritus leading to an improvement of clinical signs observed in otitis externa.

Terbinafine is an allylamine with a pronounced fungicidal activity. It selectively inhibits the early synthesis of ergosterol, which is an essential component of the membrane of yeasts and fungi including *Malassezia pachydermatis* (MIC_{90} of 2 µg/ml). Terbinafine has a different mode of action than azole antifungals, therefore there is no cross resistance with azole antifungals.

Florfenicol is a bacteriostatic antibiotic which acts by inhibiting protein synthesis. Its spectrum of activity includes Gram-positive and Gram-negative bacteria including *Staphylococcus pseudintermedius* (MIC_{90} of 8 µg/ml).

Due to the high antimicrobial concentrations achieved in the ear canal and the multifactorial nature of otitis externa, *in vitro* susceptibility may not be directly correlated with clinical success.

5.2 Pharmacokinetic particulars

The formulation dissolves in ear wax and is slowly eliminated from the ear mechanically.
Systemic absorption of all active substances was determined in multiple-dose studies after placing the veterinary medicinal product into both ear canals of healthy mixed breed dogs. Absorption occurred primarily during the first two to four days after administration, with low plasma concentrations (1 to 42 ng/ml) of active substances. The extent of percutaneous absorption of topical medications is determined by many factors including the integrity of the epidermal barrier. Inflammation can increase the percutaneous absorption of veterinary medicinal products.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E 321)
Hypromellose
Lecithin
Oleic acid
Propylene carbonate
Glycerol formal

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Single-use multi-layered aluminium and polyethylene tube with a polypropylene thermoplastic elastomer tip.
Cardboard box containing 2, 12, 20 or 40 tubes (each tube containing 2.05 g of product of which a single dose of 1.2 g can be extracted).

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

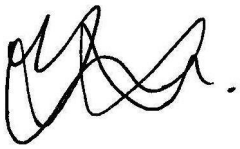
Vm 10434/5002

9. DATE OF FIRST AUTHORISATION

31 July 2014

10. DATE OF REVISION OF THE TEXT

October 2021



Approved: 19 October 2021