# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton box**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OSURNIA ear gel for dogs

terbinafine/florfenicol/betamethasone acetate

## 2. STATEMENT OF ACTIVE SUBSTANCES

1 dose: 10 mg terbinafine, 10 mg florfenicol, 1 mg betamethasone acetate

## 3. PHARMACEUTICAL FORM

Ear gel

## 4. PACKAGE SIZE

2 tubes
12 tubes
20 tubes
40 tubes

## 5. TARGET SPECIES

Dogs

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Auricular use
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP

## 11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

## 16. MARKETING AUTHORISATION NUMBER

Vm 10434/5002

## 17. MANUFACTURER'S BATCH NUMBER

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Tube**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OSURNIA ear gel for dogs

terbinafine, florfenicol, betamethasone acetate (EN or Latin)

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

10 mg terbinafine, 10 mg florfenicol, 1 mg betamethasone acetate

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

## 4. ROUTE(S) OF ADMINISTRATION

Auricular use

## 5. WITHDRAWAL PERIOD(S)

## 6. BATCH NUMBER

Lot

## 7. EXPIRY DATE

EXP

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:
# OSURNIA ear gel for dogs

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW

Manufacturer responsible for batch release:
Argenta Dundee Limited,
Kinnoull Road,
Dunsinane Industrial Estate,
Dundee
DD2 3XR,
UNITED KINGDOM

Genera Inc.,
Svetonedeljska cesta 2,
Kalinovica,
10436 Rakov Potok,
Croatia

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OSURNIA ear gel for dogs
terbinafine/florfenicol/betamethasone acetate

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One dose (1.2 g) contains 10 mg terbinafine, 10 mg florfenicol and 1 mg betamethasone acetate
Excipient: 1 mg butylhydroxytoluene (E 321)
Off-white to slightly yellow translucent gel.

## 4. INDICATION(S)

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

## 5. CONTRAINDICATIONS

Do not use in case 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 (demodectic mange).
Do not use in pregnant or breeding animals.

## 6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

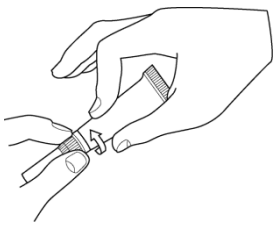
## 7. TARGET SPECIES

Dogs.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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.

## 9. ADVICE ON CORRECT ADMINISTRATION

Before the veterinary medicinal product is applied, the external auditory canal must be examined thoroughly to ensure that the ear drum is not perforated.
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.
If treatment with this product is discontinued, the ear canals should be cleaned before treatment with an alternative product is initiated.

## 10. WITHDRAWAL PERIOD(S)

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNING(S)

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.

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 and 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 package leaflet 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 Overdose).

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 veterinary medicinal product was not definitively 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.

Pregnancy and lactation:
Betamethasone is known to be teratogenic in laboratory species. The safety of this medicine has not been established in pregnancy and lactating bitches. Do not use during pregnancy and lactation.

Fertility:
Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:
Compatibility with ear cleaners, other than saline, has not been demonstrated.

Overdose (symptoms, emergency procedures, antidotes):
Prolonged or intensive use of the product may cause blistering of the tympanic membrane epithelium or mucosal ulceration in the lining of the middle ear cavity. These findings don't affect hearing and are reversible.
Prolonged and intensive use of topical corticosteroids preparation is known to trigger systemic effects, including suppression of adrenal function.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon, pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

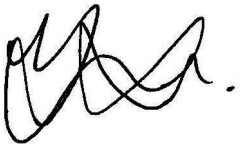
## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

This product is a fixed combination of three active substances: antibiotic, antifungal and corticosteroid.

OSURNIA ear gel for dogs is available in the following pack sizes:
1 cardboard box containing 2 tubes,
1 cardboard box containing 12 tubes
1 cardboard box containing 20 tubes
1 cardboard box containing 40 tubes
Not all pack sizes may be marketed.

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



Approved: 19 October 2021