ANNEX I

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 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.

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

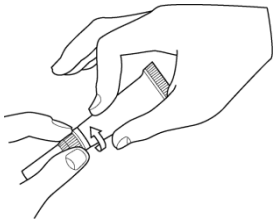
Compatibility with ear cleaners, other than saline, has not been demonstrated.

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

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/170/0001 (2 tubes)
EU/2/14/170/0002 (12 tubes)
EU/2/14/170/0003 (20 tubes)

EU/2/14/170/0004 (40 tubes)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31/07/2014
Date of last renewal: 01/07/2019

10 DATE OF REVISION OF THE TEXT

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/ .

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers 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

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/170/0001 (2 tubes)
EU/2/14/170/0002 (12 tubes)
EU/2/14/170/0003 (20 tubes)
EU/2/14/170/0004 (40 tubes)

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 Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands

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

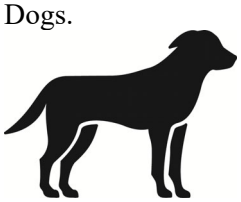
Deafness or impaired hearing, usually temporary, have been reported after use in very rare cases in dogs, mainly in elderly animals, in post authorisation experience.
Application site reactions (i.e. erythema, pain, pruritus, oedema and ulcer) have been reported in very rare cases, in post authorisation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

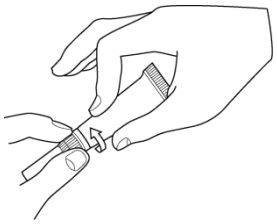
Dogs.



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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

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.