PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Audolyn Ear Drops and Cutaneous Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
miconazole nitrate 23 mg, polymyxin B sulfate 0.5293 mg, prednisolone acetate 5 mg

3. PACKAGE SIZE

15 ml

30 ml

4. TARGET SPECIES

Cats and dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For auricular and cutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Keep the container in the outer carton in order to protect from light.
Do not refrigerate.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use

Accidental spillage on the skin should be washed off immediately with soap and water.

Wash hands after use.

Corticosteroids may produce irreversible effects in the skin.

They can be absorbed and may have harmful effects, especially with frequent and extensive contact or when used in pregnancy.

Always wear single use disposable gloves when applying the product to animals.

Do not handle the product if you are allergic to any of the ingredients in the product.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 39787/5008

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Audolyn Ear Drops and Cutaneous Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
miconazole nitrate 23 mg, polymyxin B sulfate 0.5293 mg, prednisolone acetate 5 mg

3. TARGET SPECIES

Cats and Dogs.

4. ROUTES OF ADMINISTRATION

For auricular and cutaneous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Keep the container in the outer carton in order to protect from light.
Do not refrigerate.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

EU Pharmaceuticals Ltd

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Audolyn

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
miconazole nitrate 23 mg, polymyxin B sulfate 0.5293 mg, prednisolone acetate 5 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Audolyn Ear Drops and Cutaneous Suspension for cats and dogs

2. Composition

Each ml of white to off-white suspension contains:

Active substances:
23.0 mg Miconazole nitrate equivalent to 19.98 mg miconazole
5.0 mg Prednisolone acetate equivalent to 4.48 mg prednisolone
0.5293 mg Polymyxin B sulfate equivalent to 5500 IU polymyxin B sulfate

White to off-white suspension.

3. Target species

Cats and dogs.

4. Indications for use

Ear and skin treatment for cats and dogs.

This product is used in cats and dogs for the treatment of ear and skin infections caused by fungi, yeasts, Gram-negative and Gram-positive bacteria and ear mites. It will control infection due to, for example:

Gram-positive bacteria	**Fungi and yeasts**	**Ear mites**
Staphylococcus aureus	*Trichophyton spp.*	*Otodectes cynotis*
Streptococcus spp.	*Microsporum* spp.	
	Malassezia pachydermatis	
	Candida spp.	

Gram-negative bacteria
E. coli
Pseudomonas aeruginosa

For the topical treatment of otitis externa caused by the ear mite *Otodectes cynotis* and complicated by microorganisms sensitive to miconazole and polymyxin B.

The product also has anti-inflammatory and anti-pruritic activity.

5. Contraindications

Do not use:

- in cases of hypersensitivity to the active substances of the veterinary medicinal product, as well as to other corticosteroids, to other azole antifungal agents, or to any of the excipients.
- in cases of skin viral infection.
- in cases in cases of large skin lesions and of poorly healing or fresh wounds.
- in animals with perforation of the tympanic membrane.
- in animals, where resistance of causative agents to polymyxin B and/or miconazole is known.
- on the mammary glands of lactating bitches and queens.

6. Special warnings

Special warnings:
Due to likely variability (time, geographical) in the occurrence of resistance of bacteria for Polymyxin B, bacteriological sampling and susceptibility testing are recommended.

Bacterial and fungal otitis is often secondary in nature. The underlying cause should be identified and treated.

Special precautions for safe use in the target species:
In cases of persistent infestations with *Otodectes cynotis* (ear mites) systemic treatment with an appropriate acaricide should be considered.
Before treating with the product, the integrity of the tympanic membrane must be verified.
Systemic corticosteroid effects are possible, especially when the product is used under an occlusive dressing, on extensive skin lesions, with increased skin blood flow, or if the product is ingested by licking.
Oral ingestion of the product by treated animals or animals having contact with treated animals should be avoided.
Avoid contact with eyes in animals. In case of accidental contact, rinse thoroughly with water.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. This antimicrobial combination should only be used where diagnostic testing has indicated the need for simultaneous administration of each of the active substances.
Use of the product should be based on identification and susceptibility testing of the target pathogen(s).
If this is not possible, therapy should be based on epidemiological information and knowledge of the susceptibility of the target pathogens at the local or regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to prednisolone, polymyxin B or miconazole should avoid contact with the product.
The product may cause irritation to skin and eyes.
Corticosteroids may produce irreversible effects in the skin. They can be absorbed and may have harmful effects, especially with frequent and extensive contact or in pregnancy.
Avoid contact with skin or eyes. Always wear single use disposable gloves when applying the product to animals. In case of accidental contact, skin or eyes should be rinsed immediately with plenty of water. Wash hands after use.
Accidental ingestion of the product by a child may cause gastro-intestinal disturbances. Do not leave the filled dropper unattended. In case of accidental ingestion, seek medical advice immediately and show the leaflet or the label to the physician.

Pregnancy and lactation:
Use is not recommended during pregnancy. Application in the area of the mammary gland in dams with suckling infants should be avoided due to the possibility of direct drug intake by the nursing offspring.

Interaction with other medicinal products and other forms of interaction:
No data available.

Overdose:
No other symptoms than those mentioned in section 7 are expected.

Special restrictions for use and special conditions for use:
For animal treatment only.
To be supplied only on veterinary prescription.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cats and dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Deafness* Impaired hearing*

*Mainly in elderly dogs. If this occurs, treatment should be stopped. Decreased hearing or deafness is generally temporary in nature.

Prolonged use of topical steroids can cause skin discoloration and delay wound healing.
The conventional adverse effects of corticosteroids can occur (disturbance of biochemical parameters such as increased cortisol and hepatic enzyme levels).

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

For auricular and cutaneous use.

Routes of administration: For instillation in the external auditory canal or for cutaneous application.
Shake the bottle vigorously and ensure the product is fully resuspended before use.

At the beginning of treatment, hair surrounding or covering the lesions must be clipped; this should be repeated during treatment if necessary.

Ears: Clean the auditory canal and place a few drops of the product into the ear twice daily. For infections caused by *Otodectes cynotis*, instil five drops twice daily for 14 days.
Massage the ear and the auditory canal gently but thoroughly to ensure proper distribution. The success of the treatment should be verified by a veterinarian before discontinuing treatment.

Skin: Having ensured the area to be treated is clean, apply a few drops of the product (depending on lesion size) twice a day and rub well.

Treatment should be continued until a few days after complete disappearance of the clinical symptoms. In some obstinate cases, treatment may be required for 2 to 3 weeks (see also section 7). In cases where prolonged treatment is necessary repeated clinical examinations including a re-assessment of the diagnosis are required.

Where ear mite infection is present, consideration should be given to treating both ears even if infestation is only apparent in one ear.

9. Advice on correct administration

As the product is a prescription only medicine, treatment should be closely supervised by a veterinary practitioner.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.
Keep the container in the outer carton in order to protect from light.
Do not refrigerate.

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

Shelf life after first opening the immediate packaging: 3 months

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 39787/5008

Cardboard box with 1 dropper bottle of 15 ml or 30 ml and dosing dropper.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:
EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

Manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

17. Other information

POM-V

Gavin Hall

Approved: 16 October 2024