



TEMPLATE FOR RELEVANT LABEL PARTICULARS (RLPs) (Veterinary Products)

Select appropriate:

X New Product (include all applicable RLPs) OR

Variation (highlight instructions that are being varied). Approval no. of label being varied:

Signal heading:	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY
Product name:	OSURNIA Ear Gel for Dogs
Active constituent/s:	Per Tube (1.2g): 10 mg terbinafine 10 mg florfenicol 1 mg betamethasone acetate
Statement of claims:	For the treatment of acute otitis externa and acute exacerbation of recurrent otitis externa. OSURNIA Ear Gel for Dogs is indicated for the treatment of acute otitis externa and acute exacerbation of recurrent otitis externa, caused by <i>Malassezia pachydermatis</i> , <i>Staphylococcus pseudintermedius</i> , <i>Proteus</i> spp., <i>Escherichia coli</i> , and beta haemolytic streptococci. <i>Pseudomonas aeruginosa</i> is unlikely to be susceptible to florfenicol.
Net contents:	1.2 g per tube x 2 [x12; x 20; x 40]
Directions for Use Heading:	
Restrains:	USE ONLY in dogs where culture and sensitivity testing of ear swabs indicate no suitable alternatives.
Contraindications:	This product is contraindicated for use in pregnant and breeding dogs. Do not use in case of hypersensitivity to the active substances, to any of the excipients or to other corticosteroids. Do not use if the eardrum is perforated. Do not use in dogs with generalised demodicosis.
Precautions:	Bacterial and fungal otitis is often secondary to other conditions and appropriate diagnosis should be used to determine the primary factors involved. Whenever possible the use of the veterinary medicinal

	<p>product should be based on identification of infecting organisms and susceptibility testing and take into account antimicrobial policies.</p> <p>Use with precaution in dogs with a suspected or confirmed endocrine disorder (i.e. diabetes mellitus; hypo- or hyper-thyroid disease, etc.).</p> <p>If hypersensitivity to any of the components occurs, the ear should be thoroughly flushed with a non-irritating veterinary ear cleaner.</p> <p>The safety of the veterinary medicinal product has not been established during pregnancy, lactation, in breeding dogs or dogs less than 4 months of age. Use with caution in dogs less than 4 months of age.</p> <p>Systemic absorption resulting in low serum concentration of betamethasone, florfenicol, and terbinafine is unlikely to induce teratogenic, foetotoxic or maternotoxic effects at the recommended dosage in dogs.</p> <p>If use cannot be avoided, the product should be used by the veterinarian according to the risk-benefit assessment.</p>
<p>Dosage & administration:</p>	<p>Auricular use only. Administer one tube per infected ear. Repeat the administration after seven days to complete the course of treatment. Each infected ear should receive a total of two tubes, seven days apart.</p> <p>If stored under refrigerated conditions, it is recommended to allow the tube to warm to room temperature for the comfort of the dog.</p> <p>Open the tube by twisting the soft tip. Introduce this flexible soft tip into the ear canal. Empty the tube content into the ear canal by pressing it between two fingers.</p> <p>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.</p> <p>It is recommended to clean and dry the external ear canal with saline before the first administration of the product. It is recommended not to repeat ear cleaning until 14 days after the second administration of the product.</p> <p>If an alternate treatment is to be initiated then clean ears prior to administration of another veterinary medicinal product.</p> <p>Users must wear gloves when administering the product. Users must wash hands immediately after administering OSURNIA Ear Gel for Dogs.</p>
<p>General directions:</p>	<p>Veterinarians or their staff must administer the first treatment with Osurnia Ear Gel for Dogs. Veterinarians are to determine whether pet owners should administer the second treatment.</p>
<p>Safety Directions:</p>	<p>Will irritate the eyes. Avoid contact with eyes. Do not allow children to play with dosing units. If product in eyes, wash it out immediately with water. Wash hands after use.</p>
<p>First Aid:</p>	<p>If poisoning occurs, contact a doctor or Poisons Information Centre. (Phone Australia 131 126).</p>

Additional user safety:	<p>Additional User Safety Information</p> <p>If additional hazard information is required, refer to the Safety Data Sheet. For a copy phone 1800 995 709</p>
Disposal:	<p>Dispose of empty container by wrapping with paper and putting in garbage.</p>
Storage:	<p>Store between 2°C and 8°C (refrigerate, do not freeze). Protect from light. Once removed from the refrigerator, use it within 3 months and do not store it again in the refrigerator</p>

The following is for APVMA use only:

APVMA approval no.	<p>APVMA No: 69931/62085</p>
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