

VETERINARY MEDICINE

S4 MOMETAMAX®

Ear Drop Suspension

COMPOSITION

Each gram contains:

Gentamicin base (as sulphate)	3 mg
Mometasone furoate (as monohydrate)	1 mg
Clotrimazole	10 mg

Excipients

Mineral oil

PHARMACOLOGICAL CLASSIFICATION

C.14.3 Combinations (anti-infective with corticosteroids)

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Gentamicin sulfate

Gentamicin sulfate is an aminoglycoside antibiotic active against a wide variety of pathogenic Gram-negative and Gram-positive bacteria. It is an oligosaccharide antibiotic, structurally related to kanamycin, neomycin and streptomycin. *In vitro* tests have determined that gentamicin is bactericidal and acts by inhibiting normal protein synthesis in susceptible micro-organisms. Specifically, gentamicin is active against the following organisms commonly isolated from canine ears: *Staphylococcus aureus*, other *Staphylococcus* spp., *Pseudomonas aeruginosa*, *Proteus* spp. and *Escherichia coli*.



Mometasone furoate

Mometasone furoate is a synthetic adrenocorticoid for dermatologic use. Mometasone is a more recently developed corticosteroid characterised by a novel (2') furoate 17-ester having chlorine at the 9 and 21 positions, which have shown to possess high topical potency.

Clotrimazole

In studies of the mechanism of action, the minimum fungicidal concentration of clotrimazole caused leakage of intracellular phosphorus compounds into the ambient medium with concomitant breakdown of cellular nucleic acids and accelerated potassium efflux. These events began rapidly and extensively after addition of the drug.

Pharmacokinetic properties

Gentamicin is excreted primarily in unchanged form by the kidney. There is either none or very little metabolism of gentamicin in the dog. A dermal study demonstrates no meaningful absorption from skin.

Mometasone furoate is metabolised rapidly. After topical administration mometasone furoate is absorbed poorly.

Clotrimazole is excreted mainly in faeces within 48 hours. Dermal absorption of clotrimazole is very poor.

INDICATIONS

Mometamax[®] is indicated for the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin.

CONTRA-INDICATIONS

Do not use if the eardrum is perforated.

If hypersensitivity to any of the components occurs, treatment should be discontinued, and appropriate therapy instituted. Concomitant use of drugs known to induce ototoxicity should be avoided.

WARNINGS

- **Mometamax**[®] is for dogs only.
- Bacterial and fungal otitis is often secondary in nature. The underlying cause should be identified and treated.
- Use of **Mometamax**[®] should be based on susceptibility testing of isolated bacteria, and/or other appropriate diagnostic tests.
- Prolonged and intensive use of a topical corticosteroid preparation is known to trigger local and systemic effects, including suppression of adrenal function, thinning of the epidermis and delayed healing.
- Before **Mometamax**[®] is applied, the external auditory canal must be examined thoroughly to ensure that the ear drum is not perforated in order to avoid the risk of transmission of the infection to the middle ear and to prevent damage to the cochlear and vestibular apparatus.
- Compatibility with ear cleaners has not been demonstrated. Concurrent use with an ear cleaner with a high pH is not recommended.
- Wash hands carefully after applying **Mometamax**[®]. Avoid skin contact. In case of accidental exposure, rinse the affected area with copious quantities of water.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements.

Do not contaminate water, food or feed by storage or disposal.

SAFETY IN PREGNANCY AND LACTATION

Do not administer to pregnant or lactating bitches.

DOSAGE AND DIRECTIONS FOR USE

For auricular use.

Shake well before use.

Advice on correct administration

The external ear canal should be meticulously cleaned and dried before treatment. Excess hair around the treatment area should be cut.

After application, the base of the ear may be massaged briefly and gently to allow the product to penetrate the lower part of the ear canal.

Dosage

Weight of the dog	7,5 g bottle	15 g bottle
≤ 14 kg	5 drops	4 drops
> 14 kg	10 drops	8 drops

Apply to the ear once a day.

Use at room temperature (do not instill cold material into the ear).

Treatment should continue for 7 consecutive days.

SIDE EFFECTS

Mild erythematous lesions have been observed.

The use of auricular preparations may be associated with hearing impairment, usually temporary, and primarily in geriatric dogs.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinarian.

KNOWN SIGNS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Administration of recommended doses of **Mometamax**[®] beyond 7 days may result in delayed wound healing.

IDENTIFICATION

Smooth, uniform, white to off-white viscous suspension; free from foreign matter.

PRESENTATION

7,5 g or 15 g White HDPE bottle with a white LDPE cap and a white LDPE applicator. Each bottle will be packed in an outer carton.

Not all pack sizes may be marketed.

STORAGE

Store at or below 25 °C.

Store in the original bottle and carton.

Do not use the opened product after 28 days.

KEEP OUT OF REACH AND SIGHT OF CHILDREN AND UNINFORMED PERSONS.

REGISTRATION NUMBER

___/___._._ (Act 101/1965)

REGISTRATION HOLDER

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DATE OF NOTIFICATION OF APPROVAL OF THIS SCIENTIFIC PACKAGE INSERT

TBA

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