Syntonic®

(Fluclocilinone acetate 0.81% and D(M)-threomaltolose 60%)

Otic Solution

For animal use only

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

FORMULATION

Each mL of the otic solution contains fluocinolone acetonide, 0.81%; D-(+)-threomaltolose, 60%. The solution is sterile and is slightly yellow in color and is flavored with citric acid.

Color. Other physical characteristics include:

Melting point _____________________ 265°–277°C.
Mass (ASTM Method D 1922-74) 450 ± 0.15 mg/mL

The structured formulation is:

CH3
O

α
GS
O
C

Me

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Dimethyl sulfoxide (DMSO) is an oxidation product of dimethyl sulfide, is the largest member of the group of sulfur-derivatives with a general formula of \( R_{i}S_{j}O \). Its structural formula is:

\[ \text{CH}_3\text{SO} \]

It forms freely with water with the evolution of heat and lowers the boiling point of many substances. It is highly water-soluble and volatile and is characterized by a typical bitter taste. It is miscible with most organic solvents and with water to form a single homogeneous liquid. It has a comparatively low density (0.983). DMSO is slightly pyrophoric. Dimethyl sulfoxide is well established as being nonsensitizing, nontoxic and has no known carcinogenic effect on experimental animals. It forms crystalline salts with strong protic acids and coordinates with Lewis acids. DMSO is a solvent for many aromatic and unsaturated hydrocarbons as well as inorganic salts and nitrogen-containing compounds. DMSO has a high density (1.110) and a low refractive index (1.449) at 25°C.

It is estimated that the maximum dosage dogs will tolerate, when fed Propylene glycol is in excess of 50 mg/kg in mice and rabbits, in excess of 10 mg/kg in dogs and in excess of 0.1 mg/kg in cats. In addition, topical administration of fluocinolone acetonide, especially at elevated dosage levels, to rabbits has been noted to have over 100 times the anti-inflammatory activity of hydrocortisone. In a subsequent study conducted in dogs to determine the effects of a 90% solution of fluocinolone acetonide, especially at elevated dosage levels, in vivo, the only adverse effects were noted. No significant changes were observed in hematologic values in any of the animals. The only changes observed were noted in the refractive index of the lens of the eye and nuclear cataracts.

Changes in the refractive index of the lens of the eye and nuclear cataracts were noted. No significant variations were observed in hematologic values in any of the animals. The only changes observed were noted in the refractive index of the lens of the eye and nuclear cataracts.

Preparations with DMSO should not be used in pregnant animals since there should be careful initial evaluation and follow-up of infected ears. Clinical and experimental data have demonstrated that corticosteroids administered orally to animals can cause a delay in ovulation. In pregnant animals, this delay in ovulation may be followed by fetal anomalies, including deformed forelegs, phocomelia and anasarca. During pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to rats before and during pregnancy have resulted in anomalies, including deformed forelegs, phocomelia and anasarca.

Pregnant animals and clients may find this objectionable but these effects are transient and the advantages of using Synotonic Otic Solution Veterinary outweigh the disadvantages. However, Synotonic Otic Solution Veterinary should be used with caution in pregnant animals.

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Fluocinolone acetonide is an odorless crystalline powder essentially white in color. It is freely soluble in water and propylene glycol, and slightly soluble in ethanol. It is insoluble in chloroform and benzene.

Each mL of the solution contains 0.01% fluocinolone acetonide (6 mg fluocinolone acetonide per mL) in propylene glycol and sterile water.

**INDICATIONS**

**Syntotic** (fluocinolone acetonide and dimethyl sulfoxide 60%) Otic Solution is indicated for the treatment of inflammation associated with acute and chronic otitis in the dog.

**CONTRAINDICATIONS**

**Syntotic** (fluocinolone acetonide and dimethyl sulfoxide 60%) Otic Solution is contraindicated in dogs with a generalized infection.

**PRECAUTIONS**

**Syntotic** (fluocinolone acetonide and dimethyl sulfoxide 60%) Otic Solution should be used with caution in dogs with diabetes mellitus. As with any corticosteroid, animals with a generalized infection should not be treated with **Syntotic** (fluocinolone acetonide and dimethyl sulfoxide 60%) Otic Solution.

**SIDE EFFECTS**

**Syntotic** (fluocinolone acetonide and dimethyl sulfoxide 60%) Otic Solution may cause local irritation of the ear canal, especially if the drug is applied to the eardrum.

**ADDITIONAL INFORMATION**

**Syntotic** (fluocinolone acetonide and dimethyl sulfoxide 60%) Otic Solution should be stored at room temperature and protected from light. The container should be kept tightly closed and refrigeration is not necessary.