

For the use of Registered Veterinary Practitioner, Hospital or Laboratory

FONDATONE®

(Mometasone Furoate Topical Solution USP)

Composition:

Mometasone Furoate IP 0.1% w/w
In a lotion base q.s.

Dosage form: Topical Solution (Lotion)

Indications: It is indicated for the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

Dose and administration: Shake well before use. Clean and dry the affected area before administering the product. Administer one dose (1 dropperette) per affected area.

Remove the caps from the bottle. Apply a thin film to the affected skin areas once daily. Discontinue therapy when control is achieved. If no improvement is seen within 2 weeks, reassess diagnosis

Do not use with occlusive dressings unless directed by a physician

It should be administered by veterinary personnel. Persons near the animal (dogs, cats) during administration should also take steps to avoid ocular exposure.

Contraindications: It is contraindicated in dogs or cats with known or suspected hypersensitivity to Mometasone Furoate.

Special warnings and precautions for use:

Human Warnings: Mometasone Furoate Topical Solution may cause eye injury and irritation. If contact with eyes occurs, flush copiously with water for at least 15 minutes. If irritation persists, contact a physician. Humans with known hypersensitivity to active ingredients should not handle this product. Not for use in humans. Avoid skin contact. In case of accidental ingestion by humans, contact a physician immediately.

Precautions: For use in animals only. Do not administer orally.

Drug Interactions: Not applicable

Undesirable effects: In a field study conducted, there were no directly attributable adverse reactions in dogs administered Mometasone Furoate Topical Solution.

Mechanism of Action: Mometasone furoate is a glucocorticosteroid with anti-inflammatory activity. Like other topical corticosteroids, mometasone furoate has anti-inflammatory, anti-pruritic, and vasoconstrictive properties. Mometasone furoate monohydrate is a synthetic adrenocorticoid characterized by a novel (2) furoate 17-ester having chlorine at the 9 and 21 positions, which have shown to possess high topical potency.

In laboratory animals, mometasone furoate exhibits potent topical anti-inflammatory activity but approximately half of the suppressive effect on the HPA (hypothalamic-pituitary-adrenal) axis when compared with equivalent doses of betamethasone valerate. The topical to systemic potency ratio of mometasone furoate is approximately 3 to 10 times that of betamethasone valerate in animal studies.

Pharmacokinetic Properties: Systemic absorption of mometasone furoate solution was found to be minimal (2%) over 1 week when applied topically to dogs with intact skin. In a 6-month dermal toxicity study using 0.1% mometasone solution on healthy intact skin in dogs, systemic effects typical of corticosteroid therapy were noted.

Incompatibilities: Not known

Presentation: Pack of 30 ml.

Storage: Store between 20°C – 25°C (68°F – 77°F), excursions are permitted 15°C – 30°C (59°F – 86°F). Keep the container tightly closed after use.

Keep out of reach of children.



SAVA HEALTHCARE LIMITED

Plot No. 507-B to 512 GIDC Estate,
Wadhwan City – 363035, Surendranagar,
Gujarat, India

www.savavet.com