

## Feline Mucosalate™ (Brand of Orafate™) Prescribing Information

FDA 510k 123904 – Cleared August 2013

### Prescribing Information - Product Package Insert

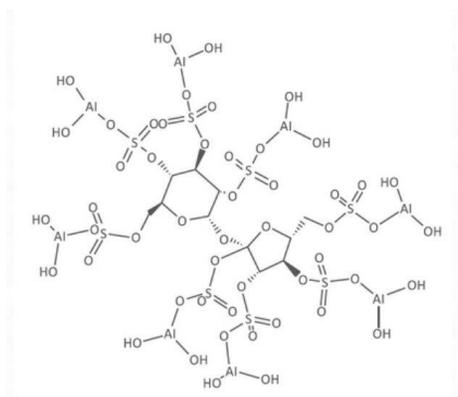
Feline Mucosalate™ (Brand of Orafate™) - Polymerized Cross-linked Sucralfate Paste. Prescription Only by veterinary dentists and veterinary physicians for cats

Medical Device UPC



#### Description of Device:

Feline Mucosalate™ is a 10% sucralfate paste. Sucralfate is an  $\alpha$ -D-glucopyranoside,  $\beta$ -D-fructofuranosyl-, octakis-(hydrogen sulfate), aluminum complex, molecular weight of 2,086.75 having the following structure:



Water containing calcium chelated malic acid added to sucralfate powder converting sucralfate granules into a polymerized paste.

**Ingredients:** Sucralfate, xanthan gum, calcium sulfate, purified water, calcium carbonate, methyl parabens, propyl parabens, malate, sodium saccharin, cod liver oil flavor

**Contents:** Feline Mucosalate™ paste in a 75 cc bottle.

**FDA Indications:** Mucosalate™ (Brand of Orafate™) Sucralfate Malate Paste forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. The paste may be used in the management of mouth lesions of all types in cats including those caused by periodontal and gingival inflammation, tooth extractions, traumatic wounds and wounds associated with oral surgery.

**Contraindications:** The administration of Mucosalate™ is contraindicated in patients with a known or suspected hypersensitivity to any of its ingredients.

**Special precautions for use:** Do not use any product bottle that is not intact or otherwise damaged in any way.

**For Oral Use:** Feline Mucosal fate™ is not intended for ingestion but for the management of oral ulcerations, oral irritations or oral mucosal wounds in cats.

**Direction of use:**

Feline Mucosal fate™ paste comes in a 75 cc bottle.

- **Treatment of Oral Ulcerations/Stomatitis:** Mouth dosing is 1.5 cc (or more). Using an oral syringe apply aliquots of paste to affected areas twice a day for the first day and then once daily until ulcerations are gone.
- **Periodontal (gum) Treatment:** Using a soft finger brush, apply an aliquot of paste to the junction of tooth and gum, twice a day for the first day and then once daily until treatment is complete.
- **Treatment of Incidental Wounds:** Using a soft finger brush apply an aliquot of paste to the wound twice a day for the first day and then once daily until wound is healed.
- **Alternative Use:** Mucosal fate™ can be mixed in a 1:1 ratio with wet food per dose and given so as to move around the mouth with their tongue.

**Length of Use:** Mucosal fate™ is to be used no longer than the time prescribed by the veterinary dentist or physician, ideally no longer than the period of time wherein the oral wound, irritation or inflammation persists.

**Side effects:** At the time of this writing, no adverse side effects have been reported with the use of Mucosal fate™ on cats.

**Adverse Reaction:** Adverse reactions to sucral fate products in cats has not been established.

**Warning:** Federal law restricts Mucosal fate™ to sale by or on the order of a veterinary dentist or veterinary physician.

**Storage:** Store at controlled room temperature 20-25°C (68-77° F) out of direct sunlight. Do not use after the expiration date shown on the jar.