

MuGard[®]

Oral Mucoadhesive

Description: MuGard[®] Oral Mucoadhesive is a mucoadhesive product. When swirled gently around the mouth, the mucoadhesive formulation results in the formation of a protective coating over the oral mucosa. The device is supplied in plastic bottles and is designed for the management of oral wounds such as mucositis, stomatitis, aphthous ulcers and traumatic ulcers.

Ingredients: Purified water, glycerin, benzyl alcohol, sodium saccharin, Carbomer Homopolymer A, potassium hydroxide, citric acid, polysorbate 60 and phosphoric acid.

Contents: Each plastic bottle contains 8 fluid ounces of oral mucoadhesive.

Indications: *MuGard* is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces.

Contraindications: *MuGard* is contraindicated in patients with known hypersensitivity to any of the ingredients in the formulation.

Directions for Use: Gently pour 5 mL of *MuGard* into the mouth and rinse the entire oral cavity for a minute or longer if possible. If the action of rinsing is inconvenient or too painful, *MuGard* can be spread throughout the mouth by a gentle rotating action of the head. Ensure that all parts of the oral cavity have been coated with the rinse. If necessary, up to 10 mL may be used to fully coat the inside of the mouth. After rinsing, excess rinse may be expelled or swallowed.

For the management of oral mucositis/stomatitis, it is recommended that *MuGard* is used 4-6 times a day. It is recommended that patients purchase *MuGard* prior to the commencement of cancer therapy.

For other ulcerative conditions of the oral cavity, *MuGard* should be used 4-6 times a day or as needed.

Mode of Operation: *MuGard* is formulated to adhere to the mucosal surface of the mouth and thereby forms a soothing, protective layer.

Special Precautions for Use: Avoid eating or drinking for at least one hour after rinsing with *MuGard*. After use, replace the bottle cap and tightly seal the bottle. Do not use this product after the expiration date shown on the product label. Do not use this product in patients with a known sensitivity to any of product's ingredients. Dilution of the product prior to use is not recommended.

Interactions with other Medicinal Products: There are no known adverse interactions of this product with other medicinal products.

Storage: Store this product at room temperature out of direct sunlight.

Clinical Studies: A clinical study of *MuGard* was conducted in patients undergoing radiation therapy for treatment of head and neck cancer. Some patients in the study were also being treated with chemotherapy. The patients in the study used *MuGard* throughout the course of radiation therapy.

Oral Care: Good oral hygiene, especially as recommended by a physician, should be used in addition to the use of *MuGard*.

Overdose: No cases of overdose have been reported at the time of producing this leaflet.

Pregnancy: There have been no adequate and well controlled studies of the use of *MuGard* in pregnant animals or in pregnant women.

Pediatric Use: There have been no adequate and well-controlled studies of the use of *MuGard* in pediatrics.

Geriatric Use: Safety and effectiveness of *MuGard* in geriatric patients have not been established.

Caution: Federal law restricts this device to sale by or on the order of a physician or properly licensed medical practitioner.

RX ONLY

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