



MuGard® Oral Mucoadhesive 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.

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

For the management of oral mucositis (OM):

Proven. Proactive. Protection.

OM is a side effect of many cancer treatments

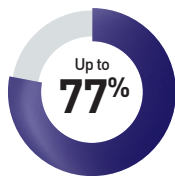
By tumor type



Head and neck cancer receiving radiation therapy¹



Hematopoietic stem cell transplant²



Breast cancer³

By targeted therapy



Everolimus⁴

For additional data on OM incidence, go to MuGard.com.

Proven efficacy

- MuGard significantly reduced mouth and throat soreness compared with saline bicarbonate rinse (control) in a multicentered, randomized, double-blind trial in patients undergoing chemotherapy and/or radiation therapy^{5,6}
- Incidence of unanticipated adverse device effects was similar in the MuGard and control groups⁵

AUC ^a	MuGard (n = 37 ^{5,b})	Control (n = 41 ^{5,b})	P value (ANOVA) ^c
Mean (SD)	68.0 (39.74)	86.1 (34.30)	0.034
Median	59.5	80.0	

21% reduction in mouth and throat soreness as a difference in mean AUC⁵

ANOVA: analysis of variance; AUC: area under the curve; OMDQ: Oral Mucositis Daily Questionnaire; SD: standard deviation

^a Efficacy was evaluated in the cohort of subjects undergoing radiation therapy for head and neck cancer who received at least 1 dose per day of study rinse during the first 2.5 weeks following the start of radiation therapy (n = 78: MuGard = 37, control = 41).⁵

^b The AUC of patients' daily reported mouth and throat soreness is a measure of the total mouth and throat soreness that patients experienced during the entire course of chemoradiation therapy.^{5,7}

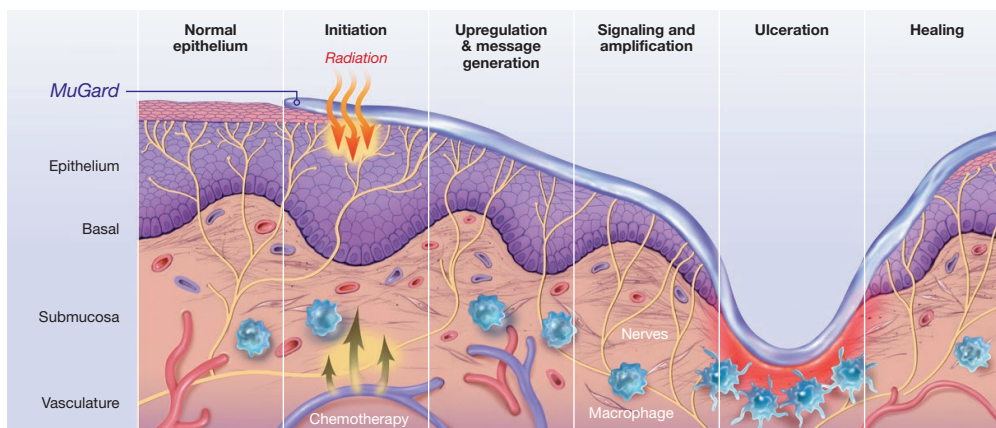
^c The AUC of OMDQ mouth and throat soreness question 2 for the two cohorts was evaluated by ANOVA with factors for treatment and initial OMDQ mouth and throat soreness score.⁵

Proactive management

- Healthcare providers should be proactive in the management of OM⁸
- Patients should obtain MuGard before their cancer therapy begins. They can start using MuGard as early as the first day of therapy and throughout their course of therapy or as directed⁹

Protection that soothes

- MuGard is a ready-to-use mucoadhesive that forms a soothing, protective coating over the oral mucosa^{5,9}



The biological stages of OM¹⁰

Please see Important Safety Information on back and accompanying full Prescribing Information, also available at MuGard.com.



Proven

A phase 4, multicentered, randomized, double-blind, placebo-controlled clinical trial that demonstrated efficacy in reducing mouth and throat soreness⁵

Proactive

Patients should obtain MuGard[®] Oral Mucoadhesive before their cancer therapy begins⁹

Protection

MuGard is a mucoadhesive formulation that forms a protective coating over the oral mucosa^{5,9}

Give patients control in managing their OM⁹

- Patients should use MuGard **4 to 6 times daily**
- **5 mL** of ready-to-use MuGard coats the oral cavity
- Up to **10 mL** can be used if needed

Patients can use MuGard as early as the first day of therapy and throughout therapy or as directed.⁹

MuGard can be swallowed or expelled⁹



Soleva
ASSIST

For more information on how to obtain MuGard, contact Soleva Assist at **866-900-5634**

Indication and Important Safety Information

Indication: MuGard[®] Oral Mucoadhesive 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.

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

Please see accompanying full Prescribing Information, also available at MuGard.com.

References: 1. Trotti A, Bellm LA, Epstein JB, et al. Mucositis incidence, severity and associated outcomes in patients with head and neck cancer receiving radiotherapy with or without chemotherapy: a systematic literature review. *Radiother Oncol.* 2003;66(3):253-262. 2. Fernandes LL, Torres SR, Garnica M, et al. Oral status of patients submitted to autologous hematopoietic stem cell transplantation. *Support Care Cancer.* 2014;22(1):15-21. 3. Nishimura N, Nakano K, Ueda K, et al. Prospective evaluation of incidence and severity of oral mucositis induced by conventional chemotherapy in solid tumors and malignant lymphomas. *Support Care Cancer.* 2012;20(9):2053-2059. 4. Afinitor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2015. 5. Allison RR, Ambrad AA, Arshoun Y, et al. Multi-institutional, randomized, double-blind, placebo-controlled trial to assess the efficacy of a mucoadhesive hydrogel (MuGard) in mitigating oral mucositis symptoms in patients being treated with chemoradiation therapy for cancers of the head and neck. *Cancer.* 2014;120(9):1433-1440. 6. Data on file, Soleva Pharma, LLC. 7. Daly CF. Easing the effects of radiation therapy to the head and neck. *Oncol Nurse Advisor.* 2013; September/October:17-32. 8. National Cancer Institute. Oral complications of chemotherapy and head/neck radiation-for health professionals (PDQ®). <http://www.cancer.gov/about-cancer/treatment/side-effects/mouth-throat/oral-complications-hp-pdq#section/all>. Updated April 23, 2014. Accessed December 15, 2015. 9. MuGard [package insert]. NJ, Soleva Pharma, LLC., 2020. 10. Sonis ST. The pathobiology of mucositis. *Nat Rev Cancer.* 2004;4(4):277-284.



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