

# MuGard<sup>®</sup>

Mucoadhesive Oral Wound Rinse

## Information for Nurses



## Help the patients you care for manage the suffering of oral mucositis (OM)

### The MuGard<sup>®</sup> benefits

1. *MuGard* is a viscous liquid formulated to adhere to the inner surface of the mouth and form a soothing, protective coating over the oral mucosa.<sup>1</sup>
2. The efficacy of *MuGard* has been demonstrated in a randomized, multicenter, double-blind, sham-controlled trial.<sup>2</sup>
3. *MuGard* was statistically superior to saline/bicarbonate rinse (“sham”), a current standard of care.<sup>2</sup>
4. *MuGard* significantly reduced OM-associated mouth and throat soreness (MTS) in evaluable patients.<sup>2</sup>
5. Access to *MuGard* is easy for patients and healthcare professionals through the *MuGard* Patient Reimbursement Service Center (MPRSC).

### Indication and Important Safety Information

**Indication:** MuGard<sup>®</sup> Mucoadhesive Oral Wound Rinse 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.



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## The ulcerative lesions of OM are among the most common, devastatingly painful, and debilitating side effects of cytotoxic cancer therapy<sup>3</sup>

The severity and course of OM are worsened for patients undergoing total-body irradiation or when radiation is concomitant with chemotherapy.<sup>4</sup>

- Ulcers may begin to manifest as early as 3 days after treatment begins and can last 2 to 4 weeks after treatment is concluded<sup>4</sup>

While patients suffering from OM can experience great difficulty eating, drinking, swallowing, speaking, and even sleeping,<sup>5</sup> the risks associated with OM go beyond the agonizing discomfort:

- Dose-limiting OM can become a barrier to lifesaving cancer therapy<sup>3</sup>
- OM can result in a 4-fold increase in unplanned delays to radiation therapy<sup>6</sup>
- OM may adversely affect outcomes by increasing the risk for streptococcal or candida infection<sup>6</sup>

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## MuGard<sup>®</sup> is easy for your patients to use

It is recommended that patients purchase *MuGard* prior to the commencement of cancer therapy for use 4 to 6 times a day.<sup>1</sup> *MuGard* may be used throughout the course of therapy.

**Directions for use<sup>1</sup>:** Gently pour 5 mL of *MuGard* into the mouth, and rinse the entire oral cavity for 1 minute, or longer if possible. If the action of rinsing is inconvenient or too painful for patients, they can gently rotate their head to spread *MuGard* throughout the mouth. Ensure that all parts of the oral cavity have been coated with the rinse. If needed, up to 10 mL may be used to fully coat the inside of the mouth. After rinsing, excess rinse may be expelled or swallowed.

**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 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.

# Working together to manage the suffering of oral mucositis



## A recent study comparing *MuGard* to sham\* set a new standard for assessing the clinical usefulness of OM treatments<sup>2</sup>

### Analysis populations<sup>2</sup>

Safety	Assessed in ITT population undergoing radiation therapy for treatment of head and neck cancer	<b>N = 121</b>
	<b>MuGard, n = 61</b>	<b>Sham, n = 60</b>
Efficacy	Assessed in patients who received at least 1 dose of study rinse within 2.5 weeks of starting radiation therapy	<b>n = 78</b>
	<b>MuGard, n = 37</b>	<b>Sham, n = 41</b>

Safety in the 7-week study was evaluated in the ITT population that included 121 subjects (equal numbers received *MuGard* and sham) who received study rinse, regardless of the duration of dosing. The efficacy parameters of the study were assessed among the cohort of subjects who received at least 1 dose of study rinse during the first 2.5 weeks following the start of radiation therapy (n = 78: *MuGard* = 37, sham = 41).<sup>2</sup>

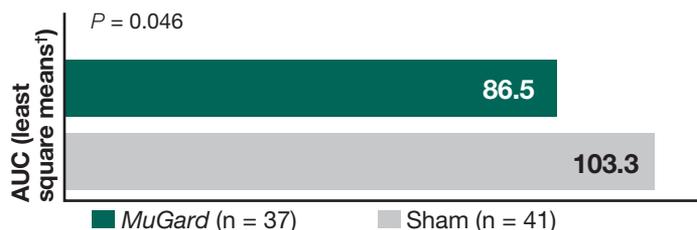
\*Sham was saline/bicarbonate rinse representative of a current standard of care.<sup>2</sup>

### Primary end point

- To evaluate efficacy of *MuGard* in reducing the symptoms of OM, as determined by the area under the curve (AUC) of Oral Mucositis Daily Questionnaire (OMDQ) mouth and throat soreness question 2<sup>2</sup>

## *MuGard* significantly managed the suffering caused by OM<sup>2</sup>

### AUC for MTS question 2 by treatment<sup>2</sup>



<sup>†</sup> The least square means are based on an ANOVA model with fixed effects for treatment and lowest MTS question 2 score prior to onset of a > 2 score.<sup>2</sup>

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*Working together to manage the suffering of oral mucositis*

## **Counsel your patients about the importance of good oral hygiene when undergoing cancer treatment<sup>1,7</sup>**

Frequent oral assessments are particularly important for patients undergoing chemotherapy in order to detect and monitor OM progression.<sup>8</sup> Patients can be advised to support their own well-being by doing the following<sup>9</sup>:

- Brushing their teeth gently with a soft-bristle toothbrush 2 to 3 times daily
- Increasing fluid intake (make sure to wait 1 hour after rinsing with MuGard<sup>®1</sup>)
- Avoiding foods that may irritate their mouth (such as spicy foods, citrus foods or drinks, tomatoes, and salted chips)
- Applying moisturizer to their lips frequently
- Cleaning their dentures daily and removing them often to expose their gums to air
- Not using tobacco products

## **AMAG Pharmaceuticals makes it simple to get MuGard for your patients**

The *MuGard* Patient Reimbursement Service Center (MPRSC) works to deliver *MuGard* directly to patients. Healthcare professionals can have confidence that prescriptions will be filled by licensed pharmacists and shipped directly to patients.

## **To order MuGard, follow these two simple steps:**

- 1.** Prescribing physician completes and signs the prescription form in the Patient Starter Kit (prescription order form can also be downloaded from MuGard.com).
- 2.** Completed form is faxed to **877-591-2505** or **216-591-2505**.

Remember, one bottle lasts about a week. When completing the prescription form, the prescribing physician should indicate the initial quantity to be dispensed (**typically six 8-oz bottles**). Additional refills may be required depending on the cancer regimen and length of treatment. For more information, contact the MPRSC toll-free at **888-514-7828**.

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

**References:** **1.** MuGard [package insert]. Dallas, TX: Access Pharmaceuticals, Inc.; 2010. **2.** Data on file, AMAG Pharmaceuticals, Inc. **3.** Rubenstein EB, Peterson DE, Schubert M, et al. Clinical practice guidelines for the prevention and treatment of cancer therapy-induced oral and gastrointestinal mucositis. *Cancer*. 2004;100(suppl 9):2026-2046. **4.** Epstein JB, Thariat J, Bensadoun R-J, et al. Oral complications of cancer and cancer therapy: from cancer treatment to survivorship. *CA Cancer J Clin*. 2012;62(6):400-422. **5.** Sonis ST. *Oral Mucositis*. London, United Kingdom: Springer Healthcare; 2012. *Pocket Books for Cancer Supportive Care*. **6.** Vera-Llonch M, Oster G, Hagiwara M, Sonis S. Oral mucositis in patients undergoing radiation treatment for head and neck carcinoma: risk factors and clinical consequences. *Cancer*. 2006;106(2):329-336. **7.** National Cancer Institute. Oral complications of chemotherapy and head/neck radiation (PDQ<sup>®</sup>): oral mucositis, health professional version. <http://www.cancer.gov/cancertopics/pdq/supportivecare/oralcomplications/HealthProfessional/page5>. Updated February 28, 2013. Accessed August 19, 2013. **8.** Bensinger W, Schubert M, Ang K-K, et al. NCCN Task Force Report: prevention and management of mucositis in cancer care. *J Natl Compr Canc Netw*. 2008;6(suppl 1):S1-S21. **9.** Mucositis. The Oral Cancer Foundation. <http://www.oralcancerfoundation.org/treatment/mucositis.html>. Updated December 28, 2012. Accessed August 20, 2012.



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