# Science. Applied to Life.™

## **3M<sup>™</sup> Xerostomia Relief Spray**

RN49878-6000-2

Xerostomia Relief Spray

Relieves symptoms

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RXONIY

**Technical Data Sheet** 

## Background

Saliva is a complex fluid, composed of water, enzymes, hormones, antibodies and antimicrobials.<sup>1</sup> Saliva naturally decreases friction, and its ability to lubricate is an important aspect for oral health, processing food, taste perception and patient comfort.<sup>2,3</sup> Saliva is very important for maintaining good oral health, but most patients generally don't consider its presence or how vital it is to their health until they've lost it.1

## Xerostomia

Xerostomia, otherwise known as dry mouth, can create uncomfortable and harmful effects on the mouth including: a sticky, dry feeling in the mouth and throat; trouble chewing, swallowing, tasting and speaking; a burning sensation in the mouth; cracked, dry lips; a dry, rough tongue; mouth sores; an increased risk of infections; tooth decay; and bad breath. These symptoms can have a major impact on the patient's quality of life.

Xerostomia has many causes. One of the most common causes is the use of medications. More than 700 prescription and over-the-counter medications have been identified as causing xerostomia.<sup>3,4</sup>

Some common medications that may cause xerostomia include:<sup>5</sup>

- Anti-acne agents
- Antianxiety agents
- Anticonvulsants
- Antidepressants
- Antidiarrheal agents
- Antidysrhythmics
- Antihistamines
- Antinausea agents
- Antipsychotics

- Anorexiants
  - Antacids
  - **Bronchodilators**

**Diuretics** 

- Decongestants
- High blood pressure
- medications
- Muscle relaxants
- Narcotic analgesics

- Nonsteroidal antiinflammatory drugs (NSAIDs)
- Opioid analgesics
- Parkinson's disease medications
- Sedatives
- Smoking-cessation agents
- Urinary incontinence agents

Cancer treatments, such as chemotherapy and head and neck radiation, may damage the salivary glands and greatly diminish saliva flow. Other conditions that may affect saliva glands include Sjögren's syndrome, HIV/AIDS, nerve damage, hypertension, hepatitis C, lymphoma, diabetes, dehydration, smoking and mouth breathing.<sup>4,5</sup>

Xerostomia is a subjective feeling, and patients may complain of dry mouth even if they don't have salivary dysfunction or an actual reduction in saliva volume. In this case, xerostomia may be a result of changes in the overall quality of the saliva produced by the salivary glands.<sup>1,6</sup>

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More than 700 prescription and over-the-counter medications have been identified as causing xerostomia.<sup>3,4</sup>



## 3M<sup>™</sup> Xerostomia Relief Spray

3M<sup>™</sup> Xerostomia Relief Spray is a professional-grade solution designed to provide rapid, effective and convenient relief of xerostomia symptoms. It's simple to use, and patients can apply it wherever they are, at any time of day. It's available only by prescription through a dental professional.

Xerostomia Relief Spray utilizes oxygenated glycerol triester (OGT) technology and is a lipid-based solution. It is designed to lubricate the entire oral cavity, including the oral mucosa, the tongue and the throat. The lipid film formed by 3M Xerostomia Relief Spray limits water loss and provides relief of symptoms for up to 4 hours.

Each prescription contains two, 10 mL aluminum spray vials, which equates to a 28-day supply.



### Indications

3M Xerostomia Relief Spray is intended to provide relief from chronic and temporary xerostomia (dry mouth).

### Composition

3M Xerostomia Relief Spray creates a protective lipid film consisting of oxidized glycerol triesters, silicon dioxide, sugar-free sweetener and flavoring.

### Benefits at a glance:

- Available by prescription only through a dental professional
- Provides rapid relief
- Relieves symptoms of xerostomia for up to 4 hours
- Lipid-based spray moistens and lubricates the mucosa

- Improves the ability to chew, taste, swallow and speak
- Easy and convenient spray application



Relieves symptoms of xerostomia for up to 4 hours

#### Evidence

#### **Proven Clinical Performance**

The safety and efficacy of OGT technology have been proven in clinical trials. Study results demonstrate a significant improvement in the symptoms of xerostomia including: chewing, swallowing, taste and speech.<sup>7,8</sup> Patients enrolled in clinical trials tested OGT spray, and researchers compared their responses to patients who used an aqueous-based saliva substitute. The clinical trials focused on geriatric patients, patients with medication-induced xerostomia and patients who had received head and neck radiation therapy.<sup>7,8,9</sup>

In all three clinical trials, OGT spray was shown to provide significant benefits to most patients. A majority of patients in the medication-induced xerostomia clinical trial said OGT spray enhanced both their ability to chew (73 percent) and swallow (65 percent). Eighty four percent of the patients said it also improved their quality of life. OGT spray also lasted longer, with 78 percent saying they used it three to four times per day and only 19 percent saying they used it four or more times per day. The taste of the spray was considered good for both products but far better for OGT spray (mean score 7.2 for the OGT spray vs. 5.5 for the aqueous-based spray). Eighty seven percent of the patients reported that they felt better from using OGT spray and that it was easy to use. There were no unpleasant or adverse effects for 94 percent of patients who used OGT spray, and 78 percent said they wished to continue using the product. The researchers concluded that the lubricating and protective qualities of OGT, in comparison with an aqueous solution, improved the feelings of dry mouth and improved many important factors related to patients' quality of life, which can be severely affected by xerostomia.8

Published in the Cochrane Database of Systematic Reviews, a 2011 review comparing xerostomia interventions concluded that lipidbased OGT technology shows greater effectiveness when compared to water-based electrolyte sprays.<sup>10</sup>

Laboratory testing designed to mimic the effects of xerostomia products on soft tissue confirms the efficacy of OGT technology. Using novel in vitro test methods to measure lubricity and moisture retention, researchers at 3M and the University of Minnesota School of Dentistry conducted comparative experiments of OGT spray and some common, commercially available xerostomia products.<sup>11,12</sup>



#### Lubricity

The University of Minnesota has developed a reciprocating mechanical system, which models the relative movement of the mandibular and maxillary structures in the mouth and was used to study the friction between simulated hard and soft oral tissues in the presence of various xerostomia relief products.<sup>11</sup> Using either dry tissue or tissue lubricated only with water as controls, researchers were able to measure the coefficient of friction, otherwise known as lubricity, for each product and found that OGT spray was the most efficient at lubricating the hard tissues tested. In the experiment, the mean coefficients of friction were significantly different between all groups tested. The mean coefficient of friction of OGT spray was four times lower than the hard tissue controls that were left dry.<sup>11</sup>



Lubricity

#### **Moisture Retention**

Researchers at 3M have found a unique way to test for moisture retention. They found that OGT spray performed statistically better at preventing water loss when tested against many commercially available xerostomia relief products. Using a technique named thermogravimetric analysis, which measures moisture loss over time at specific temperatures, researches used samples of sirloin steak to represent human soft tissue and coated them with xerostomia relief products. As the temperature of the test instrument is increased to body temperature, the sirloin steak begins to lose water. After four hours at body temperature, the percentage of weight lost by each sample can be measured and converted into the percentage of total water lost after four hours. The sirloin steak samples coated with OGT spray showed significantly less water loss compared to many competitive xerostomia products. This low level of water loss suggests a moisture-protective effect that the OGT spray exhibits on intraoral tissues. OGT spray was able to prevent water loss and provide more lubricity than any of the other products tested.<sup>12</sup>



#### Water Loss after 4 Hours at 37°C



### **Application Technique**

- (1) Shake dispenser gently.
- (2) Spray one dose (2 sprays) into the mouth 3 to 4 times a day.
- 3 Spread product onto inflamed and/or dry areas of the mouth with the tongue.

It may take up to 3 days to fully experience relief from xerostomia. It is important to use 3M<sup>™</sup> Xerostomia Relief Spray regularly for best results.

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