



U.S. Patent: 8,367,650

Rx Only – Prescription Medical Device

INGREDIENTS: Oxidized glycerol triesters (TGO), silicon dioxide, aspartame, and artificial flavoring.

ACTIONS: Aquoral® is a lipid-based solution resembling human saliva designed to moisten and lubricate the oral cavity, including the oral mucosa of the mouth, tongue and throat, by formation of a lipid film which limits loss of water and restores the viscoelasticity of the oral mucosa. Aquoral also provides protective action against further inflammation of the oral mucosa. Xerostomia (dry mouth) has harmful effects on the oral cavity and quality of life; consequently, management of dry mouth is primarily based on relief of symptoms.

INDICATIONS: Aquoral is intended to provide relief from chronic and temporary xerostomia (dry mouth), which may be a result of disease such as Sjögren's Syndrome, oral inflammation, medication, chemo or radiotherapy, stress or aging. Aquoral relieves symptoms of dry mouth such as difficulties in swallowing, speech, and changes in taste.

CONTRAINDICATIONS: Aquoral is contraindicated for any patient with a known history of hypersensitivity to any of its ingredients.

PRECAUTIONS: Read package insert carefully before using this spray. Avoid contact with eyes. Flush eyes with water if accidental introduction into eyes should occur.

INTERACTIONS: There are no known interactions with medicinal or other products.

DIRECTIONS FOR USE: Shake gently. One dose (2 sprays) into the mouth 3 to 4 times a day. Spread product on to inflamed and/or dry areas of the mouth with the tongue. Pump may require priming for initial use.

To report a serious adverse event or obtain product information call (800) 531-3333.

HOW SUPPLIED: Aluminum canister with 0.1 ml spray pump containing 40 ml (1.4 fl. oz.) (net content) of solution which corresponds to 400 sprays of Aquoral (NHRIC 0178-0420-40).

KEEP OUT OF REACH OF CHILDREN.



Manufactured for:
MISSION PHARMACAL COMPANY
San Antonio, TX USA 78230 1355

MADE IN FRANCE

Aquoral® artificial saliva is a medical device registered with the United States Food and Drug Administration.



At temperatures
over 315°C / 599°F