

ORAL RINSES

(Aquoral, Bocasal, Caphosol, (tablet & solution), Episil, Gelclair, Gelx, Mucotrol, Mugard, Neutrasal, Numoisyn, Oramagicrx, Salicept, SalivaMax, SalivateRx)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Disruptions in the function and/or integrity of the mucosal lining of the gastrointestinal (GI) tract are a particularly important problem in patients receiving chemotherapy and/or radiotherapy. Oral mucositis/stomatitis (mouth sores) is the principal manifestation of acute oral toxicity related to chemotherapy, while much less commonly, xerostomia (dry mouth) results. Among the other potential oral consequences of chemotherapy are infection of oral soft tissues, gingival bleeding, and alterations in taste; all of these complications can cause pain and impair nutrition (1). Mucositis is a self-limiting condition, and currently there is no agent available to consistently prevent or treat this condition. The goal is to decrease the severity and duration of mucositis, to provide relief of discomfort, and prevent or treat infection until recovery. The use of antibacterial and antifungal oral rinses is one of the approaches used to manage oral mucositis (2).

Regulatory Status

FDA-approved indications: Oral rinses are indicated for:

1. Relief from chronic and temporary xerostomia caused by Sjogren's syndrome, oral inflammation, medication, chemo or radiotherapy, stress or aging (3).
2. Relief from symptoms of dry mouth (ex. Difficulties in swallowing, speech and changes in taste) (3).
3. Adjunct to standard oral care in treating oral mucositis caused by radiation or high dose chemotherapy (4).
4. Dryness of the mouth (hyposalivation) or throat (xerostomia) regardless of the cause or whether the conditions are temporary or permanent (4, 10).
5. Mucosal protection (5, 6).
6. Management of oral mucosal pain and protection from further irritation caused by oral mucositis/stomatitis (resulting from chemotherapy or radiation therapy); irritation; lesions, periodontal and gingival inflammation, tooth extractions, and wounds due to oral surgery; chafing; minor lesions; traumatic ulcers, and abrasions caused by braces/ill-fitting dentures or disease; diffuse aphthous ulcers (canker sores) (5).
7. Management of pain and relief of pain by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiation therapy) irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, or disease. Also indicated for diffuse aphthous ulcers (6, 8, 9).

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8. Oral mucositis caused by radiation or chemotherapy (10).
9. Dryness of oral mucosa from hyposalivation caused by surgery, radiotherapy, chemotherapy, infection or dysfunction of salivary gland; emotional factors-anxiety or fear; salivary gland obstruction; Sjogren's syndrome (10).
10. Dryness of oral mucosa from drugs such as antihistamine, atropine and anticholinergic agents (10).
11. Xerostomia (11).
12. Treatment of mouth sores, mouth irritation and canker sores (11).

Summary

Oral mucositis or stomatitis is the principal manifestation of acute oral toxicity related to chemotherapy, while much less commonly, xerostomia results. Mucositis is a self-limiting condition, currently there is no agent available to consistently prevent or treat this condition. The goal is to decrease the severity and duration of mucositis and to provide relief of discomfort, and to prevent or treat infection until recovery. The use of antibacterial and antifungal oral rinses is one of the approaches used to manage oral mucositis (1-12).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of oral rinses while maintaining optimal therapeutic outcomes.

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