

Frequently Asked Questions

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What is Oral Mucositis (OM)?

OM is an inflammation of the oral mucosa. It is a debilitating and cytotoxic side effect of antineoplastic chemotherapy and radiotherapy. It is one of the most severe side effects of antineoplastic therapy.

Who is at risk of OM?

OM varies with the type of cancer therapy. It affects:
40% of patients receiving chemotherapy
80% of patients receiving HSCT and
almost 100% of all patients who undergo head and neck cancer radiotherapy

In addition, almost 15% of patients who receive chemotherapy and about 43% or more of patients receiving head and neck RT will develop severe mucositis.

How is OM Diagnosed?

According to its severity, OM is classified in 5 grades – Grade 0 to Grade 4; The scale plays a critical role in communication among oncologists for the clinical management of OM.

OM scoring guide

Grade 0	None; No incidence of OM
Grade 1	Mild OM; Oral soreness accompanied by erythema
Grade 2	Moderate OM; Oral erythema, ulcers, solid diet tolerated
Grade 3	Severe OM; Deep oral ulcers, Patients can take a liquid diet only
Grade 4	Severe Life threatening OM; Oral alimentation impossible

Adapted from WHO oral toxicity scale.

The National Cancer Institute Common Toxicity Criteria (NCI-CTC) scale measures anatomical and functional components of mucositis similar to those measured by the WHO oral toxicity scale.¹

Severe mucositis – as classified by Grade 3 and Grade 4, is also referred to as pseudomembranous mucositis or ulcerative mucositis.

The concomitant administration of chemotherapy, during head and neck radiotherapy may increase the severity of mucositis.

¹ National Cancer Institute Common Toxicity Criteria. Version 2.0, June 1, 1999. Available at: <http://ctep.info.nih.gov>. Accessed January 20, 2005.

How is OM detected visually?



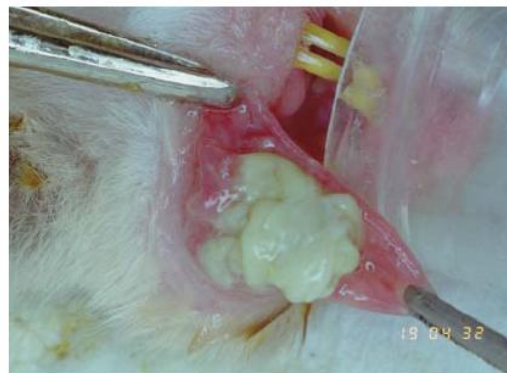
A. Score of 0. *The pouch is completely healthy with no erythema or vasodilation.*



D. Score of 3. *Formation of ulcer occupying 1/4 or less of the pouch.*



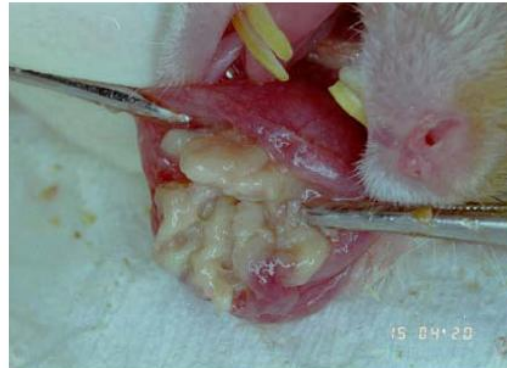
B. Score of 1. *Light to severe erythema and vasodilation with no erosion of the mucosa.*



E. Score of 4. *Total size of ulcer occupies 1/2 of the pouch with loss of pliability.*



C. Score of 2. *Severe erythema and vasodilation with erosion and decreased stippling of superficial mucosa leaving denuded areas.*



F. Score of 5. *Ulceration to virtually all of the pouch.*

How is OM treated?

Currently, there are no treatments for OM; Kepivance is the only drug approved for OM for HSCT patients – which accounts for only 5% of patients who develop OM.

About AP002

What is AP002?

AP002 is a synthetic protein that is produced through laboratory processes to mimic the activity growth factors. AP002 is a type of growth factor that stimulates the activity of epithelial cells which line and protect the oral mucosa. Therefore, the stimulation and growth of epithelial cells through AP002 may provide a prophylactic treatment for the prevention of oral mucositis.

What is AP002 Mechanism of Action?

AP002 is a growth factor that binds to the EGF receptor. This results in the proliferation, differentiation, and migration of epithelial cells to deficient sites and helps in wound healing. These receptors are present in many tissues examined including the buccal mucosa, the linings of the esophagus, stomach and intestines etc.

AP002 has demonstrated favorable results for the prevention and treatment of chemotherapy and radiation induced mucositis. Specifically, it acts at the stem cell level and is a therapeutic agent to resolve mucosal injuries through cell regeneration and initiating cyto-protective measures. It protects the mast cells against cytotoxic treatment, inhibit production of pro-inflammatory cytokines such as IL-1 β , IL-6 and TNF- α , and inhibits enterocyte apoptosis through attenuation of Bax gene and stimulation of Bcl-2 which exacerbate mucositis.

AP002 can be a “Standard of Care” for the prevention and treatment of radiation and chemotherapy induced mucositis.

How is AP002 administered?

AP002 is administered topically – preferably as a mouthwash or a rinse, given 2-3 days before the administration of chemotherapy or radiation therapy. For additional convenience, patients can use the mouthwash at home, thereby saving valuable hospital resources and physician time.

Which tumors is AP002 effective for?

AP002 can be developed in various formulations for a variety of solid tumors, including head and neck cancers.

What is the dose regimen for AP002?

AP002 has been found to be effective at 3 μ g/dose level for all major pre-clinical studies conducted by APS. The exact dosage and the regimen will be established during the clinical trials.