

CLINIDENT-PERIO-CHEM®

20mL Class I Medical Device for the treatment of Oral Mucositis



Physiopathology of Oral Mucositis: Oral mucositis is a very common side effect of gingivitis, periodontal disease, peri-implantitis and cancer chemotherapy. The oral mucosa being one of the fastest growing tissues in the body, the cytostatic effect of dental plaque or cancer therapies on oral mucosa cells blocks cellular growth, affects immune responses, and causes oral mucositis. >20 proteolytic enzymes (MMPs) are secreted to clean the oral lesion but they also destroy the extra-cellular matrix (ECM) & stop gingival epithelial cell growth. Microbial growth then ensues, causing inflammation and further halting cellular repair.

Ideal Treatment Approach: 1. Clean the lesion/ulcer of microbial contaminants 2. Reduce the local concentration of the Extra-cellular Matrix-destroying MMPs (Matrix Metallo-Proteinases) to provide an intact cellular matrix for new cell growth. 3. Organize the maintenance protocol to reduce bacterial growth and excess MMPs.

Currently Available Treatments: Only symptomatic treatments (antiseptics, anesthetics, growth factors...)

Completely NEW Therapeutic Approach: Provide a clean, hydrated microenvironment to allow ulcer healing and reduce pain.

Employing *in vitro* technology, VITROBIO discovered & patented a hypertonic viscous liquid solution, based on Glycerol: VB-Gy, 18 times more osmotically active than sea water yet NON-IRRITANT, capable of generating an instant flow of hypotonic liquid when applied on a live biological, semi-permeable, membrane (International patent 1997: PCT/FR99/01340). Applying this solution on the ulcers cleans the injury of all the contaminants present on the ulcers within a few minutes. The filmogen capacity of this solution was enhanced to resist local movements (2013 patent: PCT/EP2013/061835).

When applied as a thin layer on the Mucositis ulcer, PERIO-CHEM® instantly forms a film & creates a strong outward flow of hypotonic liquid, instantaneously detaching all the contaminants, healing-impeding impurities and all undesirable infiltrated particles from the injury. A clean environment reduces pain and leads to a restored ECM which rapidly supports healthy cell growth so that the healing process may resume, allowing partial lesion/ulcer healing, and minimizing new mucositis ulcer formation & expansion.

Product Presentation: 20mL spray.

Posology: 4-5 sprays every 2 h in the beginning of treatment, then 3-4 times a day during the maintenance period.

Regulatory Status: Due to the mechanical topical filmogen activity without any pharmacological, biological, metabolic or immunological interaction with the cellular structure: Class I Medical Device in Europe.

Contraindications: Not to be used in the pediatric population under 3 years of age. Totally safe during pregnancy or lactation.

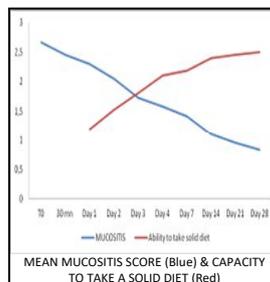
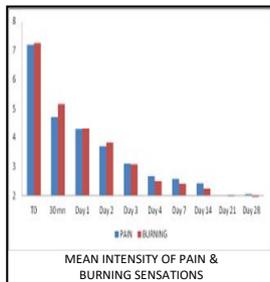
Side Effects: Slight burning sensation for about 1 min following product application.

Clinical Efficacy: Full article in *J Cancer Res & Treatment* (1) 4-11, 2013. DOI: 0.12691/jcrt-1-1-2.

Clinical Trial Protocol:

4-week, controlled trial
7-91 age group,
Male & Female patients,
Induced Oral Mucositis
Perio-Chem group: n= 48
Control (Classical treatments) group: n= 21
4-5 daily applications

Parameters measured:
Overall Mucositis Grade
Pain
Burning Sensation
Bacterial or Fungal Infection
New Ulcer Formation
Eating Difficulty



Conclusion:

Marked reduction in mucositis grade

Marked reduction of the infection

Marked reduction in pain

