

# Treatment of oral mucositis pain by a bioadhesive barrier forming lipid solution.

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## Objectives

Oral mucositis is a common side-effect of radiotherapy and chemotherapy of cancer. It is frequently a painful condition with ulceration of the mucous membranes and opportunistic infections in the mouth. In severe cases, it can be extremely painful and may necessitate hospitalization for opioid pain medication and parenteral nutrition or even interruption of radiotherapy, which will compromise the final results. Development of a locally acting analgesic product with long effect duration would improve the well-being of a large group of cancer patients.

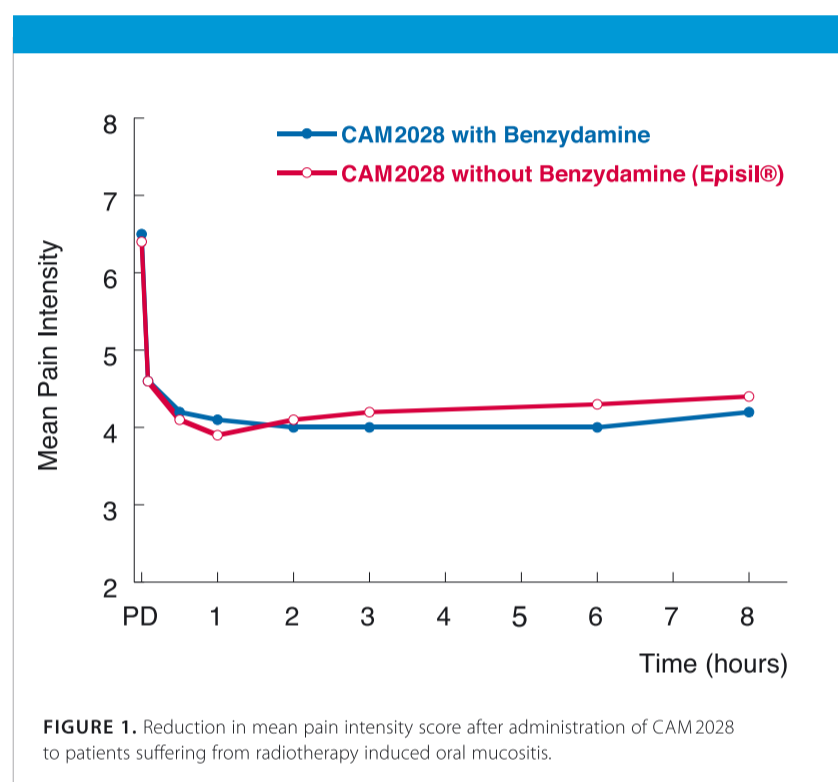
The current study<sup>1</sup> investigated intra-oral pain intensity before and up to eight hours after intra-oral administration of a bioadhesive barrier forming lipid solution. The study included treatment using lipid solution both with and without the active ingredient benzydamine.

## Methods

- Multicentre, randomized, double-blind, single dose, cross-over study
- More than 24 hours wash-out period between treatments
- Patients undergoing radiation therapy for treatment of head and neck cancer (N=38)
- Patients having oral mucositis of grade 2 or above (WHO scale) in week 3 to 4 of radiotherapy
- Assessment of oromucosal pain intensity (0-10 Likert pain score) before and 5 min, 30 min, 1h, 2h, 3h, 6h and 8h after dosing
- Treatments
  - CAM2028 with benzydamine
  - CAM2028 without benzydamine (Episil®)
- Objectives
  - To demonstrate at least 6 hrs analgesic effect of a single dose
  - To assess safety and tolerability

## Results

Evaluations of pain intensity versus time demonstrated an immediate treatment effect of the bioadhesive and barrier forming lipidsolution (see Figure 1). The maximum effect (mean 40% pain reduction) was reached after 1 hour and was maintained up to 8 hours. Similar treatment effects were obtained with and without benzydamine. The product was safe and well tolerated with no treatment related adverse events.



**FIGURE 1.** Reduction in mean pain intensity score after administration of CAM2028 to patients suffering from radiotherapy induced oral mucositis.

## Conclusions

CAM2028 provides an immediate and significant treatment effect maintained up to 8 hours post treatment. This relates to the effective protection of the oromucosal surfaces provided by the *in situ* barrier forming lipid solution. The unique bioadhesive and film-forming properties of CAM2028, which have been documented in a separate phase I/IIa clinical study<sup>2</sup>, isolates the sensitive irradiated mucosa from external irritation. In contrast to other barrier forming products and standard therapy, assessed under similar clinical protocol<sup>3</sup>, CAM2028 (Episil®) provides a statistically and clinically significant pain reduction for patients suffering from oral mucositis.

## References

1. Camurus AB. A randomized, two-period cross-over study, multi-centre, double-blind, single dose, placebo-controlled trial to assess the local analgesic effect of CAM2028 in head-and-neck cancer patients suffering from radiation-induced oral mucositis. Intergrated clinical and statistical report HS-05-161. (2008)
2. Camurus AB. Oromucosal benzydamine HCl – Comparison of the bioadhesion to the oral mucosa of four liquid crystalline formulations in cancer patients with oral mucositis. Clinical study report HS-05-160. (2006)
3. Barber, C., Powell, R., Ellis, A. and Hewett, J. Comparing pain control and ability to eat and drink with standard therapy vs Gelclair: a preliminary, double centre, randomized controlled trial on patients with radiotherapy-induced oral mucositis. Support Cancer Care 15:427-440. (2007)

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