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## OraCoat H-B12 Melts<sup>®</sup>: adhering discs with hyaluronan and B12 for managing mouth sores

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*H-B12 Melts* is a new product in the *OraCoat* line from OraHealth for managing mouth sores of all kinds, including sores on the tongue. It is an oral adhering disc that the patient sticks to a tooth or gingiva that is nearest the sore. The *H-B12 Melts* adhering disc slowly releases 10 mg of hyaluronan as well as a bioactive form of vitamin B12 and cellulose gum to coat the sore and protect it from irritation, relieve pain and speed healing.

The manufacturer claims that the disc lasts 1-4 hours during the day, 3-8 hours while sleeping and that it relieves pain until it finishes dissolving. The patient is instructed to place another disc whenever pain is perceived again. To minimize the pain of eating, a disc is left in place as the patient begins a meal. A new disc is then placed at the end of the meal. To speed healing, the manufacturer recommends placement of a disc while sleeping as well.

Published studies show there is therapeutic benefit from the topical application of hyaluronan and bioactive vitamin B12 to different types of oral ulceration.

### Topically applied hyaluronan

Hyaluronan, also called hyaluronic acid or sodium hyaluronate, is a linear polymer composed of repeated disaccharides of glucuronic acid and *N*-acetyl-glucosamine. There are up to 25,000 disaccharide repeating units in the length of the polymer structure. Most cells of the human body have the capacity to synthesize hyaluronan during some point in their cell cycle. Hyaluronan is constantly being formed and broken down into shorter lengths by the enzyme hyaluronidase.

The main function of hyaluronan appears to be related to tissue healing. In this process, hyaluronan is implicated in a range of activities including activation and moderation of the inflammatory responses, promoting cell proliferation, migration and angiogenesis, promotion of re-epithelialization via proliferation of basal keratinocytes and in the reduction of collagen disposition generally and with scarring (4). A number of studies have shown that the topical application of hyaluronan promotes healing of venous leg ulcers (12), nasal mucosa after surgery (16), fetal skin within the womb (8), tendons after tendon surgery (1), as well as burns, epithelial surgical wounds and chronic wounds (18).

Studies show that hyaluronan effectively treats oral ulceration as well. For example, when topically applied in the mouth to treat aphthous ulcers, a 0.2% hyaluronan gel was shown to reduce discomfort, speed healing and reduce the risk of re-occurrence (6). And, when a 0.2% hyaluronan gel was applied to both aphthous ulcers and the ulcers of Behçet's disease (5), there was a subjective reduction in the number of ulcers and a decrease in the ulcer healing period in 72% of the patients and a mean pain reduction of 76% when measured via a visual analog scale (VAS). At examination, 79% of the ulcers showed a decrease in size.

In addition to being effective for aphthous ulcers and Behçet's ulcers, topical application of 0.2% hyaluronan gel has been shown to significantly reduce the pain and size of ulcerated/erosive mucosal lesions associated with erosive lichen planus (7).

Further, topically applied hyaluronan has also been shown to be effective in managing oral mucositis (15), gingivitis (14), periodontitis (17), in the healing of tooth extraction sockets (11), and in wound healing following CO2 laser removal of premalignant lesions (9)(10).

In the above cited studies, a 0.2% gel or spray was used. The 10 mg of hyaluronan delivered from the

adhering discs of *OraCoat H-B12 Melts* will produce a 0.2% solution when dissolved in 5 grams of saliva. Because the disc is adhered close to and frequently touching the sore, it should apply a solution of at least 0.2% hyaluronan topically to the sore for at least several hours. Given the clinical evidence above, *H-B12 Melts* should be effective in reducing pain and speeding the healing of mouth sores of all kinds when they are adhered near the oral erosion or ulceration.

## Topically applied bioactive vitamin B12

Vitamin B12 is a cobalamin molecule. The daily minimum allowance recommended by the US government for B12 varies for women and men and with age. For lactating women it is 2.8 mcg per day, 2.6 mcg for pregnant women and less for others. The upper level of tolerable B12 has not been determined. The US government reports that there is no evidence of harmful effects from over consumption of vitamin B12. (20)

Absorption of methylcobalamin occurs through the mucosal or intestinal epithelium. When delivered into the blood in the most common form, cyanocobalamin, the body converts the molecule to the usable bioactive forms: methyl-cobalamin, deoxyadenosyl-cobalamin and hydroxo-cobalamin. When cobalamin is swallowed, a portion is absorbed and another portion passes through the gut and is defecated. The portion that is absorbed is distributed throughout the blood and a small amount is delivered via the capillaries to ulcerated lesions in the mouth.

*H-B12 Melts* contain 120 mcg of vitamin B12 in bioactive form (methyl-cobalamin and hydroxo-cobalamin). The B12 is slowly released into saliva close to and frequently bathing a sore. This results in a far higher concentration of bioactive vitamin B12 on the sore than can be achieved with a far higher quantity of swallowed vitamin B12 and many orders of magnitude higher level than results from swallowing the recommended daily allowance.

In studies of patients experiencing recurrent aphthous ulcers compared with age and gender matched controls, significantly higher number of aphthous subjects demonstrated B12 deficiency (2)(13). But even in the patient that does not have a B12 deficiency, the sublingual daily delivery of 1000 mcg of cyanocobalamin (before bed) over five months has been shown to significantly decreases ulcer pain, the number of ulcers, and the duration of ulcer outbreaks (19). In this study, subjects with high starting levels of B12 experienced the same results as subjects with low starting levels of B12.

Further, the daily placement in the mouth of a slowly dissolving adhering disc containing 500 mcg of the bioactive form of B12 (methyl-cobalamin) over a 30 day period was shown to significantly reduce pain from recurrent ulcers (3).

The mechanism by which methyl-cobalamin works to reduce pain and oral ulcer duration is presently unknown. However several molecular and cellular mechanisms have been proposed. Known topical physiologic effects include enhancement of nerve regeneration within a lesion and localized neutrophil activation.

The above cited studies suggest that frequent use of *OraCoat H-B12 Melts* will reduce the frequency, duration and pain of aphthous ulcers in those who are B12 deficient and may also do so in those who are not deficient. In treating oral ulceration or erosion, the manufacturer suggests that patients will most likely use 2-6 discs per day. This usage pattern will deliver 240-720 mcg of bioactive cobalamin per day directly onto the sore and surrounding mouth lining, a portion of which will be directly absorbed and the balance of which will be swallowed for absorption by the gut.

## Conclusion

*OraCoat H-B12 Melts* should work to temporarily relieve pain caused by aphthous ulceration, traumatic oral ulceration, and other conditions of mucosal erosion such as lichen planus, mucositis, gingivitis,

periodontitis, Behçet's ulcers, tooth extraction sockets, and wounds from CO2 laser removal of premalignant lesions.

The science suggests that *OraCoat H-B12 Melts* will support healthy mucosal tissue and promote mucosal healing. Ingredients include 10 mg hyaluronan, 120 mcg bioactive B12 (cobalamin), cellulose gum, acacia gum, calcium carbonate, and magnesium stearate. *OraCoat H-B12 Melts* are available over-the-counter and do not need to be prescribed.

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