

# CankerMelts® – Clinical Research Studies

**2005:** When used at the first symptom for 16 hours per day, including during sleep, CankerMelts eliminated pain in 3 days for 96% of ulcers treated.

## ORAL SURGERY, ORAL MEDICINE, ORAL PATHOLOGY, ORAL RADIOLOGY and ENDODONTOLOGY (OOOOE)

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### Studies of Licorice Extract in an Oral Patch on Minor Aphthous Ulcers

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**Objectives.** The aims of this study were: (1) to determine whether using CankerMelts containing Glycyrrhiza complex herbal extract in prolonged topical contact with RAU would shorten healing time; and (2) to compare the effectiveness at speeding healing of whole Glycyrrhiza extract (GX), reduced glycyrrhizin extract (DGL), and purified glycyrrhetic acid potassium salt (GAP).

**Study Design.** CankerMelts were supplied with 18% GX to 20 subjects, with 26% DGL to 147 subjects, and with 7.5% GAP to 40 subjects who were asked to return a report for each ulcer treated. Subjects were instructed to use the product at least 16 hours per day (while sleeping and half their awake hours) and asked to report whether the ulcer healed faster than usual, for details on usage if it did not heal within 2 or 3 days, and whether the CankerMelts disc reduced pain while in place. We received reports of trials on 30 ulcers treated with GX from 15 subjects, 49 reports of trials on 30 ulcers treated with DGL from 15 subjects, 49 ulcers treated with GAP from 46 subjects, and 14 ulcers treated with GAP from 14 subjects.

**Results.** Those receiving GX reported healing in 3 days or less on 26 out of 27 ulcers treated where the product was used as directed. In two other cases where the ulcer did not heal within 3 days, the product was used less than 16 hours per day. Of those receiving DGL, 32 reported speeding of healing and 2 reported no speeding of healing. 5 reported a failure to heal within 3 days and all 5 used the product less than 9 hours per day. For GX and DGL combined, 8 of the 9 failures to heal within 3 days (out of 64 healing time reports) resulted from using the product less than 16 hours per day. With GAP, 9 out of 14 reports found no speeding of healing, in contrast to DGL, while all 14 reported that GAP was effective for relieving pain while in place. For GX and DGL combined, out of 79 reports, 49 reported pain reduction while the CankerMelts disc was in place, 30 gave no report on pain, and no one reported a failure to reduce pain.

**Conclusions.** For most people with minor recurrent aphthous ulcers, complex Glycyrrhiza extract (GX or DGL) in a CankerMelts oral topical time release patch held in constant or frequent contact with a new aphthous ulcer for at least 16 hours per day shortens healing time for most ulcers to 1-3 days and relieves pain while in place. Purified glycyrrhetic acid potassium (GAP) relieves pain but may not reliably speed healing.

**2008:** When used 8 hours per day and not during sleep beginning 18 hours after the first symptom, CankerMelts eliminated pain in 3 days for 81% of subjects, double the amount in the no treatment group. Treated ulcers shrank by 90% over 7 days while non treated ulcers grew larger.

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### A controlled trial of a dissolving oral patch containing glycyrrhiza (licorice) herbal extract for the treatment of aphthous ulcers

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**Background:** Aphthous ulcers (RAU) are a common and painful condition. This paper describes a randomized, double blind clinical trial of an OTC medicated intraoral adhesive patch for treatment of RAU.

**Methods:** Subjects were randomly assigned to either an active drug (patch with extract of glycyrrhiza root) or placebo patch treatment group (both  $n = 23$ ) at onset of a lesion. Lesion size and pain report (unstimulated and stimulated) were assessed at intervals. A no-treatment group ( $n = 23$ ) also was recruited and assessed similarly.

**Results:** By the eighth day [seven days of treatment], the ulcer size for the active treatment group was significantly lower ( $p < 0.05$ ), while the lesions in the no-treatment group increased 13% from baseline. By the fourth day [three days of treatment], the active treatment group reported significantly less pre-stimulus pain ( $p < 0.01$ ); at this point, 81% of this group reported no pre-stimulus pain, compared with 63% of the placebo patch group and 40% of the no-treatment group.

**Conclusions:** The results of this study indicate that using an adhesive patch containing intraoral glycyrrhiza root extract for treatment of RAU offers significant benefits both in terms of reduction of pain and in visual resolution of the ulcers.

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### 2008: Review of clinical studies of treatments for aphthous ulcers.

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**Summary:** The results of the studies reviewed here suggest CankerMelts GX discs may be as effective as amlexanox (which must be prescribed) in reducing pain and speeding healing. In addition it can be applied by the patient without the adverse events associated with cyanoacrylate formulations.