

## EFFICACY OF A SUPERSATURATED CALCIUM PHOSPHATE ORAL RINSE (CAPHOSOL) IN THE TREATMENT OF XEROSTOMIA SECONDARY TO ANTIMUSCARINIC TREATMENT FOR THE BLADDER

### Hypothesis / aims of study

The primary objective of this pilot study was to evaluate the efficacy of a supersaturated calcium phosphate oral rinse (Caphosol, EUSAPharma USA, Princeton, NJ) upon the subjective global evaluation of dryness of the oral cavity in subjects with xerostomia secondary to antimuscarinic treatment for the bladder.

### Study design, materials and methods

Initial assessment of patients in this open label, prospective trial included history, physical exam, and 3 day voiding diary, with or without video urodynamics (VUDS), followed by diagnosis with either overactive bladder (OAB) or mixed urinary incontinence. Behavioural modifications were discussed and each patient included in this study was started on Tolterodine 4mg ER or Solifenacin 5mg daily. Patients were evaluated four to six weeks after starting the antimuscarinic medication. Those patients who felt improvement in their urinary symptoms but complained of dry mouth were given the Dry Mouth Questionnaire (questions 1-9, see below). Candidates were excluded from further participation if they were unwilling or unable to comply, on concomitant use of anti-xerostomia medications and preparations, being treated with an investigational medication within 30 days of completing the questionnaire, or presented with significant oropharyngeal pathology. Patients were then given a supply of Caphosol and instructions on its use. Patients were told to perform the oral rinse with Caphosol up to 7 times in a 24-hour period as needed for xerostomia. Two weeks later each patient was contacted by phone and asked questions 1-12 from the Dry Mouth Questionnaire.

### Results

After the two-week trial of Caphosol, patients stated a 45% improvement rate in overall sensation of dry mouth. The most dramatic changes were demonstrated in the mealtime dry mouth and need for liquids for swallowing with 47% and 41% improvement respectively. Average frequency of self-administration was approximately once daily but ranged from four times a day to every other day. Onset of relief was reported in 70% of patients as immediate or soon after the rinse. Eighty-eight percent of patients responded Caphosol relieved his or her dry mouth symptoms.

### Interpretation of results

Nearly half the patients who noted symptoms of dry mouth while on antimuscarinic medication found improvement while on Caphosol. In patients who experienced relief of symptoms 70% reported relief onset as rapid. Frequency of administration was less than anticipated and less than recommended for cases of oral mucositis suggesting that this may be a cost effective method of xerostomia treatment.

### Concluding message

Overall 88% of patients on antimuscarinic medication who complained of dry mouth experienced improvement of symptoms while on Caphosol. Our study was limited by small sample size, but these results justify expansion of this pilot study to determine the impact of this supersaturated calcium phosphate solution on pharmacologically-induced xerostomia.

### Dry Mouth Questionnaire

- |   |                                    |
|---|------------------------------------|
| 1. Does the amount of saliva in your mouth seem to be:                | Too little/ Too much/ Don't notice |
| 2. Does your mouth feel dry when you are eating a meal?               | Yes / No                           |
| 3. Do you have to sip liquids to aid in swallowing dry food?          | Yes / No                           |
| 4. Do you have difficulty swallowing any food?                        | Yes / No                           |
| 5. Are you thirsty?   | Yes / No                           |
| 6. Do you have sleep problems due to dry mouth/throat?                | Yes / No                           |
| 7. Do you have difficulty talking because of dry mouth?               | Yes / No                           |
| 8. Do you notice visual problems since starting the bladder medicine? | Yes / No                           |
| 9. Do you have constipation since starting the bladder medicine?      | Yes / No                           |

### Follow up questions after patient on Caphosol:

- |   |              |
|---|--------------|
| 10. How often do you need to take the Caphosol? | None / _____ |
|---|--------------|

11. When is your mouth dry?

Never / Soon after taking bladder medicine/ Always

12. Does the Cephosol relieve your dry mouth?

Yes / No

<b><i>Specify source of funding or grant</i></b>	1. Caphosol, EUSAPharma USA, Princeton, NJ -supplied study drug 2. Tiffany Sotelo, MD: Consultant for Ethicon Women and Urology Division
<b><i>Is this a clinical trial?</i></b>	Yes
<b><i>Is this study registered in a public clinical trials registry?</i></b>	No
<b><i>What were the subjects in the study?</i></b>	HUMAN
<b><i>Was this study approved by an ethics committee?</i></b>	No
<b><i>This study did not require ethics committee approval because</i></b>	Our study represented an elective treatment modality for patients with xerostomia. Patient were presented with the drug profile of Caphosol and were able select inclusion into the study or exclusion.
<b><i>Was the Declaration of Helsinki followed?</i></b>	Yes
<b><i>Was informed consent obtained from the patients?</i></b>	Yes