

**Caphosol®**  
Artificial saliva  
Prescribing Information

**Indications:** Caphosol is indicated for dryness of the mouth or throat (hyposalivation, xerostomia), regardless of the cause and regardless of whether the conditions are temporary or permanent. Caphosol is also indicated as an adjunct to standard oral care in treating the mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain.

Caphosol may be used for relief of dryness of the oral mucosa when hyposalivation results from the following: surgery, radiotherapy near the salivary glands, chemotherapy, infection or dysfunction of the salivary glands; inflammation of the mouth or throat; fever; emotional factors such as fear or anxiety; obstruction of the salivary ducts; Sjogren's syndrome; and Bell's Palsy.

Caphosol is also indicated for dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion. It may be used as part of an oral hygiene program for patients with dry mouth. Caphosol provides intensive hygiene of the oral cavity, and may be used to help relieve bad taste and to relieve offensive nasal discharge and crusting.

**Device description:** Caphosol is an electrolyte solution resembling human saliva, designed in part to replace the normal ionic and pH balance in the oral cavity. It is intended as a mouth rinse to moisten, lubricate, and clean the oral cavity including the mucosa of the mouth, tongue, and throat. Caphosol maintains moistness in the oral cavity. It relieves diffuse dryness and fissuring of the oral mucosa, as well as painful tongue conditions due to hyposalivation. Patients having this condition are also prone to dental caries and candidal infections.

Caphosol is a partial substitute for natural saliva. Caphosol facilitates chewing and speaking; loosens tough

LEA/CAS/US/1374/02

mucus; prevent mucous membranes from sticking together, helps remove nasal crust and relieve nasal soreness; improves adherence of dentures, and also relieves bad taste. Caphosol is an adjunct to standard oral care for treating mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain.

Caphosol is a preparation comprising two separately packaged aqueous solutions, a phosphate solution (Caphosol A) and a calcium solution (Caphosol B) which when both sachet solutions are combined in equal volumes form a solution supersaturated with respect to both calcium and phosphate ions.

**Ingredients of Prepared Solution (%w/w):** Dibasic Sodium Phosphate 0.032, Monobasic Sodium Phosphate 0.009, Calcium Chloride 0.052, Sodium Chloride 0.569, Purified Water 99.338.

**Precautions:** Avoid eating or drinking at least 15 minutes after use. Do not use if the seal of the sachet is broken or the sachet shows sign of leakage or damage. Contains sodium (71 mg per 30 mL dose). Patients restricted to a low sodium diet should consult their physician before use. Store at room temperature, do not refrigerate. **KEEP OUT OF REACH OF CHILDREN.**

**Caution:** Federal law restricts this device to sale by or on the order of a physician or dentist.

**Contraindications:** There are no known interactions with medicinal or other products.

**How Supplied:**

32 Dose<sup>1</sup> Box

<sup>1</sup>One Dose = 1 Caphosol A sachet and 1 Caphosol B sachet, each 15mL, mixed together.

**Directions for use:** (1) Mix 1 sachet Caphosol A and 1 sachet Caphosol B in a clean glass. (2) Swish the mouth thoroughly for 1 min with 1/2 of the solution and **spit out**. (3) Repeat with the remaining 1/2 of the solution and **spit out**. Use immediately after mixing the sachets.


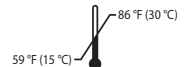




• **For use during high dose chemotherapy or radiation treatment:** 4 doses per day from the onset of the cancer treatment. Up to 10 doses per day if pain from mucositis is experienced.

Use for the duration of the treatment or as instructed by physician.

• **Relief of dry mouth:** 2-10 times per day or as instructed by physician.

If Caphosol is swallowed accidentally, no adverse effects are anticipated.

**Symbols Glossary:**

|   |   |
|---|---|
|  | Manufacturer                                |
|  | Storage condition 59 to 86 °F (15 to 30 °C) |
|  | Consult instructions for use                |
|  | Prescription use only                       |
|  | Do not re-use                               |
|  | Non sterile                                 |

**Manufactured for**  
**Recordati Rare Diseases Inc.**  
Bridgewater, NJ 08807

medinfo@recordatirarediseases.com  
Phone: 1-888-575-8344

Date of revision: June 2024

©Recordati 2024

