

Caphosol®

supersaturated calcium phosphate rinse
Prescribing Information

Ingredients: Dibasic Sodium Phosphate 0.032, Monobasic Sodium Phosphate 0.009, Calcium Chloride 0.052, Sodium Chloride 0.569, Purified Water qs ad (%w/w)

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

Actions: 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 facilitates chewing and speaking; loosens tough mucus and prevents mucous membranes from sticking together.

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.

Special precautions for use: Avoid eating or drinking at least 15 minutes after use. Do not use if the seal of the ampule is broken or the ampule shows sign of leakage or damage. Contains sodium (71mg per 30mL 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.

Interaction with other medicinal products and other forms of interaction: There are no known interactions with medicinal or other products.

How Supplied:

	Item Code
30 Dose ¹ Box	0-8489-8000-01
120 Dose ¹ Box	0-8489-8000-04

¹One Dose = 2 ampules, each 15mL, mixed together.

Directions for use: (1) Mix 1 blue (Caphosol A) and 1 clear ampule (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 ampules.

- **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.



EUSA Pharma

Manufactured by

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Caphosol® is a registered trademark of EUSA Pharma (USA), Inc.

NHRIC Labeler Code 8596

US patents no. 5993785, 6387352, patents pending

Date of revision: July 2009

730-0400R Rev. A

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phosphate rinse



C-0352-09

Catalent Pharma Solutions

INTEGRA™ 9500/9505 Verification Report

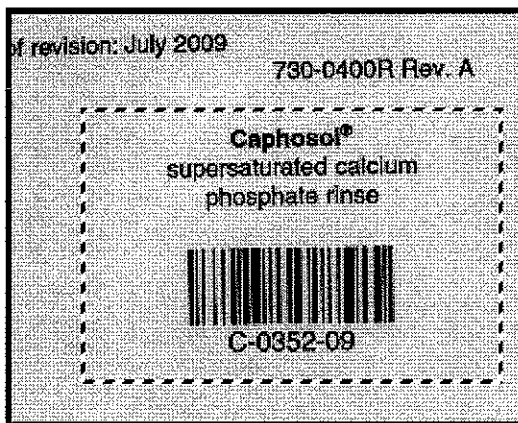
Overall: 3.5/05/660 (A)

GT 7/28/09 ^{No Spec} supplied

Operator signature

GT 7/28/09

Second signature



1D	
Symbology	Code 128
Decoded text	C035209
Xdim	11.8 mils
Edge determ	PASS
Min Reflect	PASS
Minimum EC	PASS 64%
Decode	PASS 184
Quiet zone	PASS
Contrast	4.0 (A) 81%
Modulation	4.0 (A) 79%
Decodability	3.5 (A) 62%
Defects	4.0 (A) 5%
Blemish	4.0 (A) 0%
Rmin	6%
Rmax	87%
GT	46%
Bar height	378.1 mils
Bar growth	9%

Other information	
ReportID	11791
Operator	prep (prep)
Application standard	ISO/IEC 15415/15416
Effective aperture	Reference number 05 (5 mil)
Wavelength	660nm
Date and time	28-Jul-2009 21:29 local; 29-Jul-2009 01:29 GMT
Time zone	GMT -4
Sector size	2.15" by 1.40"
Last calibration	14-Aug-2008 10:02 local; 14-Aug-2008 14:02 GMT
Field of view	2.63" (camera is 1280x1024 pixels)
Serial numbers	Unit: 60193, Camera: 31900
Software product and version	INTEGRA™ 9500 Version 3.0.5
INTEGRA™ 9500/9505 manufactured by:	Label Vision Systems, Inc. 101 Auburn Court Peachtree City, Georgia, 30269, USA www.lvs-inc.com

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