

FORMO CRESOL- cresol liquid
DSHealthcare

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Formocresol/Buckley's Formocresol

DIRECTIONS FOR USE

REF – 10606 – Formocresol – 1oz/30mL

REF – 10203 – Buckley's Formocresol – 1oz/30mL

NPN number: Formocresol – 00470236

NPN number: Buckley's Formocresol - 00470155

For dental use only.

USA: Rx only.

1. DESCRIPTION

Formocresol: 48.5% formaldehyde, 48.5% cresol, 3% glycerine. Buckley's Formocresol: 19% formaldehyde, 35% cresol, 17.5% glycerine.

2. INDICATIONS

Indicated as a disinfectant and devitalizing solution used as part of endodontic treatment.

3. CONTRAINDICATIONS

This product should not be used with individuals with known sensitivities to formaldehyde or cresol. This product should not be used with individuals who are pregnant or suspected to be pregnant without a prior physician consultation.

4. PRECAUTIONS

This product can cause severe burns of skin and mucosa. Take precautions protect skin, mucosa and eyes during use.

5. WARNINGS

Do not swallow. Do not allow material to come into contact with intact skin or mucosa. Wear eye protection when handling. Ensure proper tooth isolation, including rubber dam when applying. Keep out of reach of children. For professional dental use only.

6. DOSAGE AND ADMINISTRATION

1. Intracanal disinfection in permanent teeth: Isolate the tooth with a rubber dam. Clean, de-bridge and instrument the canals. Rinse and dry the canal spaces. Moisten a small cotton pellet with formocresol. Blot or wring any excess liquid from the pellet. Place the cotton pellet in the pulp chamber and seal the access hole with a temporary filling material. Recall the patient after a minimum of 48 hours and remove the pellet. Complete the endodontic treatment and restore.
2. Formocresol pulpotomy in primary teeth: Isolate the tooth with a rubber dam. Remove visible caries. Remove the coronal pulp with an excavator or bur leaving the radicular pulp. Achieve hemostasis. Moisten small cotton pellets with fomocresol. Blot or wring any excess liquid from the pellet. Place

the pellets directly on the radicular pulp stumps for 5 minutes. Place a base or a core in the tooth and restore.

7. STORAGE

Store between 59°-86°F (15°-30°C). Protect from freezing.

SultanHealthcare

411 Hackensack Avenue, 9th Floor, Hackensack, NJ 07601

Toll Free: 800-637-8582 • Phone: 201-871-1232

Fax: 201-871-0321 • www.sultanhealthcare.com

Made in the USA

Form #0010601DF (R 7/22/09)

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Label

Sultan[®]

REF 10601

NPN 00470236

Formo Cresol

Net Contents:

1 fl.oz. (30mL)

Warning: Corrosive. Consult MSDS for more information.

Solution may cloud below 50°F. Store at room temperature. Keep from freezing.

Contains: Formaldehyde 48.5%, Cresol 48.5%

Manufactured for: **Sultan**Healthcare

411 Hackensack Avenue, 9th Floor, Hackensack, NJ 07601 • Toll Free: 800-637-8582 • Phone: 201-871-1232

Fax: 201-871-0321 • www.sultanhealthcare.com • Imp. by VDI Healthcare, Brampton, Ontario L6W 4T5

Rx Only

For Dental Use Only

LOT

EXP

Made in USA

0010601LA (R 7/23/09)

The image shows a rectangular label for a 30 mL bottle of Formo Cresol. The label is divided into several sections. On the left, there is a blue triangular logo with the word "Sultan" in white. Below the logo, it says "Net Contents: 1 fl.oz. (30mL)" and "Rx Only For Dental Use Only". The main body of the label features the product name "Formo Cresol" in large blue letters. Below this, there is a warning: "Warning: Corrosive. Consult MSDS for more information." followed by "Solution may cloud below 50°F. Store at room temperature. Keep from freezing." and "Contains: Formaldehyde 48.5%, Cresol 48.5%". The manufacturer information is listed as "Manufactured for: Sultan Healthcare" with the address "411 Hackensack Avenue, 9th Floor, Hackensack, NJ 07601", phone "201-871-1232", and fax "201-871-0321". A red bar at the bottom contains the word "BARCODE". On the right side, the reference numbers "REF 10601" and "NPN 00470236" are printed. Below these numbers are two vertical columns of red 'X' marks. At the bottom right, it says "Made in USA" and "0010601LA (R 7/23/09)".

Sultan

Formo Cresol

Warning: Corrosive. Consult MSDS for more information.
Solution may cloud below 50°F. Store at room temperature. Keep from freezing.
Contains: Formaldehyde 48.5%, Cresol 48.5%

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REF 10601
NPN 00470236

Rx Only
For Dental Use Only

BARCODE

Made in USA
0010601LA (R 7/23/09)

PRINCIPAL DISPLAY PANEL - 1 Gallon Bottle Label

Sultan®

REF 10604

Formo Cresol

Net Contents: 1 gallon

Warning: Corrosive. Consult MSDS for more information.

Solution may cloud below 50°F. Store at room temperature. Keep from freezing.

Contains: Formaldehyde 48.5%, Cresol 48.5%

Manufactured for:

SultanHealthcare

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Rx Only

For Dental Use Only

LOT

EXP

Made in USA

0010604LA (R 7/23/09)



FORMO CRESOL

cresol liquid

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:0699-0001

Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	Cresol (UNII: GF3CGH8D7Z) (Formaldehyde - UNII:1HG84L3525)	Formaldehyde	485 mg in 1 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	Glycerin (UNII: PDC6A3C0OX)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0001-01	33.57 g in 1 BOTTLE, GLASS		
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	UNAPPROVED DRUG OTHER		02/19/1963	

FORMO CRESOL				
cresol liquid				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-0412	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	Cresol (UNII: GF3CGH8D7Z) (Formaldehyde - UNII:1HG84L3525)	Formaldehyde	485 mg in 1 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	Glycerin (UNII: PDC6A3C0OX)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0412-01	4292.19 g in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

Labeler - DSHealthcare (056296981)

Establishment

Name	Address	ID/FEI	Business Operations
DENTSPLY Caulk		083235549	MANUFACTURE

Revised: 2/2010

DSHealthcare