

CASTELLANI PAINT- phenol liquid
Stratus Pharamceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Castellani Paint

Drug Facts

Active Ingredient

Phenol 1.5%

Purpose

First Aid Antiseptic

Uses

- First aid antiseptic to help protect against skin infection in minor cuts, scrapes or burns

Warnings

For external use only

Do not use

- in eyes
- with bandages
- on large areas of the body longer than one week unless directed by a doctor
- stop use and consult a doctor if condition persists
- in case of deep puncture wounds, animal bites, or serious burns, consult a doctor
- if known to be sensitive to any ingredients in this product,

Stop use and ask a doctor or pharmacist if skin irritation or sensitivity develops or increases or the condition persists or gets worse.

When using this product

- check skin for sensitivity to phenol prior to application.
- care should be taken to avoid spilling and guard against staining. Castellani Paint Modified will stain skin and clothing.

KEEP OUT OF REACH OF CHILDREN.

Directions

- clean the affected area
- apply a small amount on the area one to three times daily.

Other Information

Store at controlled room temperature.

Inactive Ingredients

Acetone, Purified Water, Resorcinol, SD alcohol 40B (13%).

Questions or Comments?

1-800-442-7882 or visit us at www.stratuspharmaceuticals.com

Distributed by:

Stratus Pharmaceuticals Inc.
Miami, Florida 33186

PRINCIPAL DISPLAY PANEL - 29.57 mL Bottle Box

NDC 58980-820-10

Castellani Paint

modified colorless phenol 1.5%

**STRATUS
PHARMACEUTICALS INC**

FIRST AID ANTISEPTIC

NET VOL. 1.0 FL OZ (29.57 mL)

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58980-820
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Phenol (UNII: 339NCG44TV) (Phenol - UNII:339NCG44TV)	Phenol	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
ACETONE (UNII: 1364PS73AF)	
RESORCINOL (UNII: YUL4LO94HK)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	YELLOW (Clear to Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-820-10	1 in 1 BOX	04/01/2014	
1		29.57 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	04/01/2014	

Labeler - Stratus Pharamceuticals (789001641)**Establishment**

Name	Address	ID/FEI	Business Operations
TARMAC PRODUCTS INC		059890491	MANUFACTURE(58980-820) , LABEL(58980-820) , PACK(58980-820)