

AMBIX FIRST AID- dyclonine hydrochloride and phenol cream
Organics Corporation of America dba Ambix Laboratories

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.

Ambix First Aid Antiseptic & Pain Relieving Cream

Active Ingredients

Phenol 0.5%

Dyclonine Hydrochloride 0.5%

Purpose

First Aid Antiseptic

Topical Anesthetic

Uses

- first aid to help protect against infection and for the temporary relief of pain and itching associated with minor burns, minor cuts, scrapes, insect bites, or minor skin irritations.

Warnings

■ For external use only ■ Do not bandage ■ Do not use in the eyes or apply over large areas of the body ■ Do not use longer than 1 week unless directed by a doctor

Do not use in eyes, do not apply over large areas of the body. In case of deep puncture wounds or serious burns, consult a doctor.

Ask a doctor before use if you have

a deep or puncture wound, an animal bite, serious burn, or before using on a child aged 2 or under.

Stop use and ask a doctor if

redness, irritation, swelling, or pain persists or increases.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ Clean the affected area ■ Apply a small amount of this product on the area 1 to 3 times daily

Other Information

- Store at controlled room temperature 15°C to 30°C (59°F to 86°F).
- You may report serious side effects to the phone number provided under “Questions?” below

Inactive Ingredients

Allantoin, Benzyl Alcohol, Disodium EDTA, Glyceryl Stearate, Mineral Oil, Methyl Paraben, Petrolatum, Propyl Paraben, Sodium Lauryl Sulfate, Stearic Acid, Stearyl Alcohol, Triethanolamine, Water

Ambix

FIRST AID

Antiseptic & Pain Relieving Cream

Net Wt. 7/8 oz. (25 grams)

Dist. by Ambix Laboratories, Totowa, NJ 07512 ■ Made in USA ■ © 2013

Ambix

FIRST AID

Antiseptic & Pain Relieving Cream

Net Wt. 1-1/2 oz. (42.5 grams)

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FIRST AID

Antiseptic & Pain Relieving Cream

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Drug Facts

Active ingredients

Phenol 0.5%.....First aid antiseptic
Dyclonine Hydrochloride 0.5%.....Topical analgesic

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Drug Facts (continued)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Clean the affected area
■ Apply a small amount of this product on the area 1 to 3 times daily

Other information ■ Store at 15-30° C (59-86° F) ■ You may report serious side effects to the phone number provided under "Questions?" below

Inactive ingredients Allantoin, Benzyl Alcohol, Disodium EDTA, Glyceryl Stearate, Mineral Oil, Methyl Paraben, Petrolatum, Propyl Paraben, Sodium Lauryl Sulfate, Stearic Acid, Stearyl Alcohol, Triethanolamine, Water

Questions or Comments? 973-890-9002
M-Th. 9A – 3P, F 9A – 12 P EST

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AMBIX FIRST AID

dyclonine hydrochloride and phenol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10038-250
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DYCLONINE HYDROCHLORIDE (UNII: ZEC193879Q) (DYCLONINE - UNII:078A24Q30O)	DYCLONINE HYDROCHLORIDE	0.005 g in 1 g
PHENOL (UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)	PHENOL	0.005 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10038-250-25	1 in 1 BOX	08/22/2013	
1		25 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10038-250-42	1 in 1 BOX	08/22/2013	
2		42.5 g in 1 TUBE; 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	08/22/2013	

Labeler - Organics Corporation of America dba Ambix Laboratories (061061164)

Registrant - Organics Corporation of America dba Ambix Laboratories (061061164)

Establishment			
Name	Address	ID/FEI	Business Operations
Suite K Value Added Services LLC		036822144	manufacture(10038-250)

Revised: 11/2019

Organics Corporation of America dba Ambix Laboratories