MAXIM FDF- pcmx, hand soap soap Midlab Incorporated

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.



Active Ingredient

Purpose

PCMX 0.1% Antibacterial Handwashing

Uses

• Handwash to help decrease bacteria on the skin.

Warnings

For external use only.

Do not use in the eyes. In case of contact, immediately flush eyes with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply a small amount, covering hands with product for 30 seconds. Lather and rinse.
- Children under 6 years of age should be supervised when using this product.

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Inactive Ingredients

Water, Lauramine Oxide, Sodium Lauryl Ether Sulfate, 4-chloro-3, 5-dimethylphenol.

MAXIM FDF

pcmx, hand soap soap

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:70542-201

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78 V2Q) (CHLOROXYLENOL - UNII: 0F32U78 V2Q)	CHLOROXYLENOL	0.1 g in 1 L

Inactive Ingredients		
Ingredient Name	Strength	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)		
METHYLCHLORO ISOTHIAZO LINO NE/METHYLISOTHIAZO LINO NE MIXTURE (UNII: 15O9 QS218 W)		
LAURAMINE O XIDE (UNII: 4F6 FC4MI8 W)		

Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
	NDC:70542-201- 41	3.78 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/11/2019	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	03/11/2019			

Labeler - Midlab Incorporated (047371463)

Registrant - Midlab Incorporated (047371463)

Establishment				
Name	Address	ID/FEI	Business Operations	
Midlab Incorporated		047371463	manufacture(70542-201)	

Revised: 6/2019 Midlab Incorporated