

DERMESSE PAD TREATMENT 0.5- 0.5%salicylic acid lotion

DERMESSE PAD TREATMENT 2.0- 2%salicylic acid lotion

Axia Medical Solutions, LLC

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.

Dermesse Pad Treatment

Active Ingredients

0.5% Salicylic Acid

2% Salicylic Acid

Purpose

Acne Treatment

Uses:

For the treatment of acne

Warninigs:

For external use only

Combustibles. Keep away from fire or flames.

Ask a doctor or pharmacist before use if you are:

using other topical acne medications at the same time or immediately following use of this product. This may increase dryness or irritation of the skin. If this occurs only one medication should be used unless directed by a doctor.

Keep out of reach of children

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

DIRECTIONS:

- Cleanse the skin thoroughly before applying medication
- Cover the entire affected area with a thin layer one to three times daily.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every

other day.

OTHER INFORMATION:

Store at controlled room temperature 15-30°C (59-86°F), away from direct sunlight.

INACTIVE INGREDIENTS:

Ammonium Hydroxide, Edetate Disodium, Ethyl Alcohol SD40, Glycolic Acid, Propylene Glycol, Purified Water, Nonoxynol 9.

Dermesse Pad Treatment 0.5

Dermesse Pad Treatment 2.0

DERMESSE PAD TREATMENT 0.5			
0.5%salicylic acid lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68723-400
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)		SALICYLIC ACID	0.5 g
Inactive Ingredients			
Ingredient Name		Strength	
EDETATE DISODIUM (UNII: 7FLD91C86K)			
GLYCOLIC ACID (UNII: 0WT12SX38S)			

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	
AMMONIA (UNII: 5138Q19F1X)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68723-400-05	60 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	01/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/01/2022	

DERMESSE PAD TREATMENT 2.0

2%salicylic acid lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68723-401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	
AMMONIA (UNII: 5138Q19F1X)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68723-401-20	60 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	01/01/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part333D		01/01/2022	

Labeler - Axia Medical Solutions, LLC (929224694)

Registrant - Axia Medical Solutions, LLC (929224694)

Establishment			
Name	Address	ID/FEI	Business Operations
Sanitor Corporation		797472792	manufacture(68723-400, 68723-401)

Revised: 1/2022

Axia Medical Solutions, LLC