

SALICYLIC ACID- callus removers patch
Premier Brands of America Inc.

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.

Premier Solutions Callus Removers

Active ingredient

Salicylic acid 40%

Purpose

Callus remover

Use

- for the removal of calluses
- relieves pain by removing calluses

Warnings

For external use only.

Do not use

- if you are a diabetic
- have poor blood circulation
- on irritated skin, on any area that is infected or reddened

If discomfort persists

Keep out of reach of children.

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

Directions

- wash affected area and dry thoroughly
- if necessary, cut medicated patch to fit callus
- carefully adhere medicated patch directly over callus
- cover medicated patch with pad
- after 48 hours, remove medicated patch
- repeat procedure every 48 hours as needed for up to 14 days (until callus is removed)
- may soak callus in warm water for 5 minutes to assist in removal

Other information

store between 15°C to 30°C (59°F to 86°F)

Inactive ingredients

acrylic adhesive, acrylic polymer, polyethylene, polyvinyl alcohol

Questions?

call 1-866-964-0939

Principal Display Panel

Premier

CALLUS REMOVERS

Salicylic Acid

Effective callus removal treatment

Protects against pressure & friction

MEDICATED

6 PADS/4 MEDICATED PATCHES



SALICYLIC ACID

callus removers patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56104-244
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	40 mg in 4

Inactive Ingredients

Ingredient Name	Strength
POLYVINYL ALCOHOL (UNII: 532B59J990)	
VINYL ACETATE (UNII: L9MK238N77)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56104-244-01	4 in 1 PACKAGE; Type 0: Not a Combination Product	06/16/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358F	06/16/2022	

Labeler - Premier Brands of America Inc. (117557458)

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