SALICYLIC ACID- medicated callus removers extra thick patch
Chain Drug Consortium, 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.

Premier Value Extra Thick 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
- if you have poor blood circulation
- on irritated skin, on any area that is infected or reddened

Stop use and ask a doctor

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 area thoroughly
- if necessary, cut medicated patch to fit callus
- apply adhesive side down of medicated patch onto 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 corn is removed)
- may soak corn 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 Value

Extra Thick
CALLUS REMOVERS

Salicylic acid

- Callus removal treatment
- Relieves against pressure & pain

4 MEDICATED PATCHES/4 PADS

SALICYLIC ACID

medicated callus removers extra thick patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-230

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:68016-230-04	4 in 1 PACKAGE; Type 0: Not a Combination Product	02/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358F	02/12/2018	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - Premier Brands of America (063849780)

Establishment

Name	Address	ID/FEI	Business Operations
Premier Brands of America		080051232	relabel(68016-230) , repack(68016-230)

Establishment

Name	Address	ID/FEI	Business Operations
Alchemix Corporation		615263956	manufacture(68016-230)

Revised: 12/2019 Chain Drug Consortium, LLC