SALICYLIC ACID- medicated callus removers patch
Hudson Health 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.

Comfortzone Medicated Callus Removers

Active ingredient

Salicylic acid 40%

Purpose

Callus remover

Uses

- 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

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 thoroughlyif 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 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 1-877-237-0194

Principal Display Panel

comfortzone

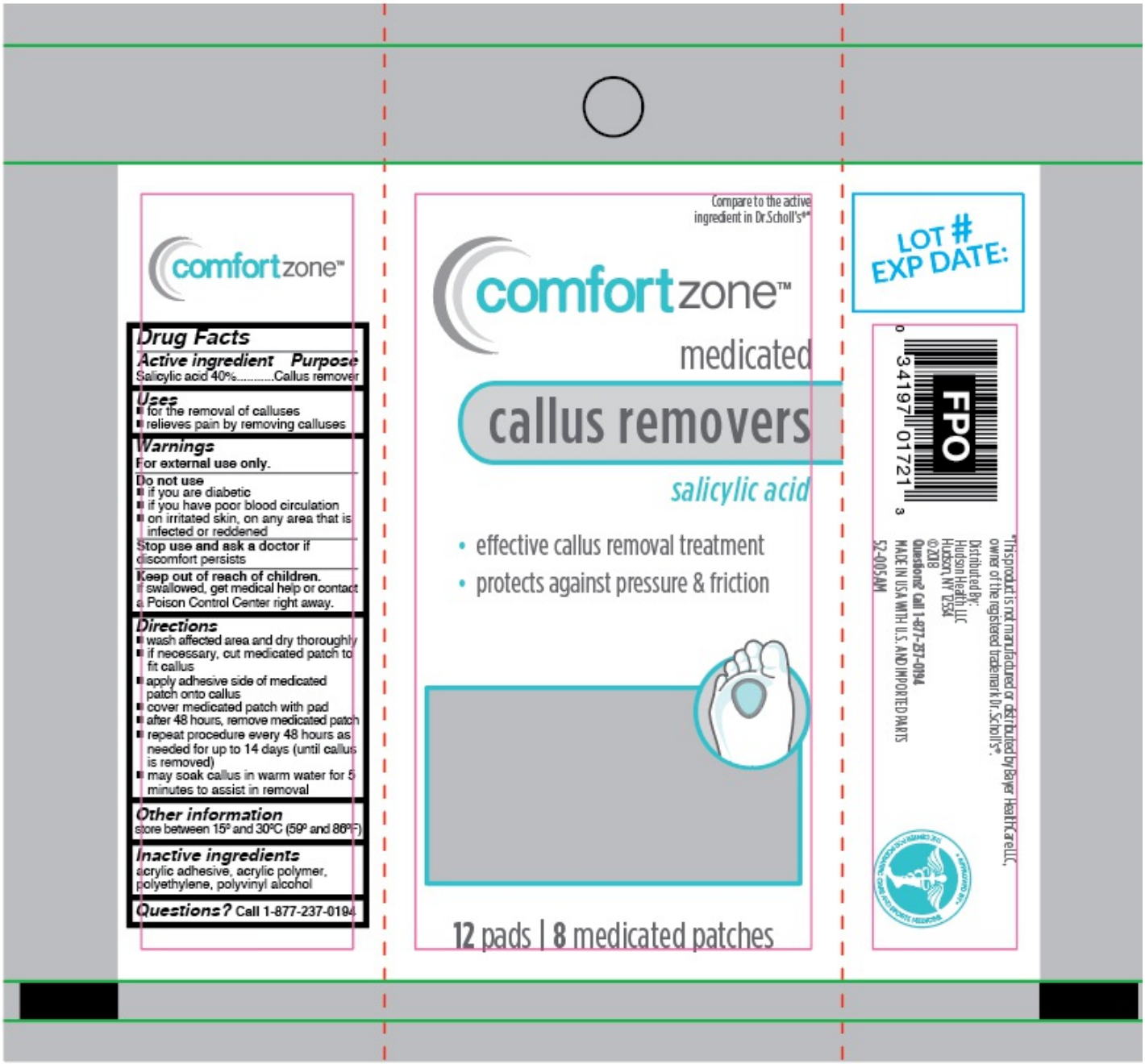
medicated

callus remvoers

salicylic acid

- effective callus removal treatment
- protects against pressure & friction

12 pads/ 8 medicated patches



SALICYLIC ACID

medicated callus removers patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72446-001
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 8

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72446-001-08	8 in 1 PACKAGE; Type 0: Not a Combination Product	08/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358F	08/31/2018	

Labeler - Hudson Health LLC (081276171)

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