## ONE STEP WART REMOVERS- salicylic acid disc Scholls Wellness Company 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.

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### **One Step Wart Removers**

Active Ingredient

Salicylic acid 40%

Purpose

Wart Remover

• for the removal of common wart. The common wart is easily recognized by the rough 'cauliflower-like' appearance on the surface

### For external use only

- if you are a diabetic
- if you have poor blood circulation
- on irritated skin or any aea that is infected or reddened
- on moles, birthmarks, warts with hair growing from them, genital warts, or warts on the face or mucous membranes

Stop use and ask a doctor if discomfort lasts

Keep out of reach of children.

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

- wash affected area and dry thoroughly
- apply medicated bandage
- after 48 hours, remove medicated bandage
- repeat procedure every 48 hours as needed for up to 14 days (until wart is removed)
- may soak wart in warm water for 5 minutes to assist in removal
- store between 20° to 25°C (68° to 77°F)
- protect from excessive heat and temperatures above 40°C (140°F)

## Inactive ingredients

Antioxidant (CAS 991-84-4), iron oxides, mineral oil, petroleum hydrocarbon resin, silicon dioxide, synthetic polyisoprene rubber, talc

Questions?

1-866-360-3226



### **ONE STEP WART REMOVERS**

salicylic acid disc

Salley lie dela disc						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (So	urce)	NDC:7346	59-6321	
Route of Administration	TOPICAL					
	_					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of St	trength	Strength	
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)			SALICYLIC ACII	D	0.4 g in 1 g	
Inactive Ingredients						

Strength

**Ingredient Name** 

BROWN IRON OXIDE (UNII: 1N032N7MFO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MINERAL OIL (UNII: T5L8T28FGP)	
ANTIOXIDANT GS (UNII: 2BBL73FIEU)	
TALC (UNII: 7SEV7J4R1U)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Product Characteristics				
Color	brown	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73469- 6321-4	14 in 1 CARTON	05/31/2023	
1		1 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
OTC monograph final	M028	05/23/2023		

# Labeler - Scholls Wellness Company LLC (117174744)

# Registrant - Scapa Tapes North America LLC (079995435)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Scapa Tapes North America Inc.		079995435	manufacture(73469-6321)	

Revised: 5/2023 Scholls Wellness Company LLC