

**SCHOLLS WELLNESS COMPANY LLC DURAGEL CALLUS REMOVER- 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.*

-----

**Duragel Callus Remover**

**Drug Facts**

Drug Facts

**Active Ingredient**

Active Ingredient Purpose

Salicylic Acid 40%..... Callus remover

**Purpose**

Callus remover

**Uses**

Uses

for the removal of calluses  
relieves pain by removing calluses

**Warnings**

Warnings

For external use only

Do not use

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

**Stop use and ask a doctor**

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.

## Directions

Directions

wash affected area and dry thoroughly

if necessary, cut medicated disc to fit callus

apply medicated disc with sticky side adhering to skin

cover medicated disc with enclosed cushion

after 48 hours, remove medicated disc

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

Other information

store between 20°C to 25°C (68° to 77°F).

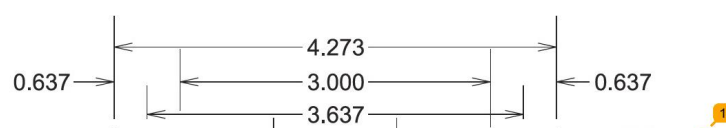
Protect from excessive heat (temperatures above 40°C (104°F)

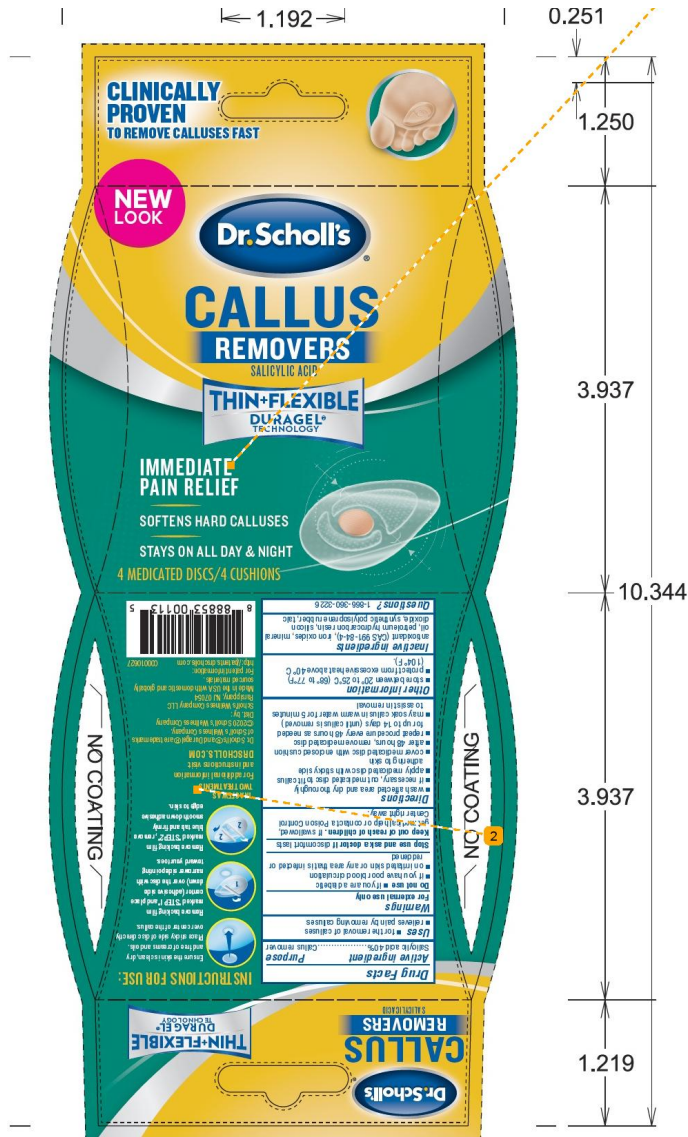
## Inactive Ingredients

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

## Questions

Questions? 1-866-360-3226





ARTWORK		Scholl's Client: Scholl's Wellness Company		Printing Inks		Non-Printing		DRUG FACTS INFO (Updated 5/10/16)	
			Project Type: New Product Launch	1	Magenta	6	PMS 2045	<input type="checkbox"/> color	<b>CATEGORY</b>
Job #: 439614	Version: 3	Brand: Dr. Scholl's		2	Yellow	7	PMS 328	<input type="checkbox"/> flexo	Drug Facts Title
Diadels CSR: EF	Oper/Date: FL 10-21-20	Scholl's/Sub Brand/Bozage Form: P000013011-DURAGEL CALLUS REMOVER-4 COUNT		3	Black		Gloss Varnish	<input type="checkbox"/> screen	Drug Facts Continued
Printer: Ellis Paper Box		Item#: C00010827	File: BY1956	4	Cyan		Emboss 1	<input type="checkbox"/> offset	Headings*
Printer Location:		EPC LEAM/UPC: 888953001135	BPC Specs: M: 80% H: .42"	5	PMS 116		Matte Varnish	<input type="checkbox"/> hot stamp	Subheadings
<b>All Images/Codes are FPO</b>		File Name: 439614_C00010827_DS_4ca_Dta_v3	Software: Illustrator 2017					<input type="checkbox"/> digital	Block Text
		<b>NOTE: THIS COLOR PROOF INDICATES COLOR BREAK ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRODUCTION COLOR.</b>						<input type="checkbox"/> dry offset	Bullets
									Leadlines
									Headlines
									One and Halflines
									Chatterboxes Per Inch

# SCHOLLS WELLNESS COMPANY LLC DURAGEL CALLUS REMOVER

salicylic acid disc

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73469-0644
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.4 g in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANTIOXIDANT GS</b> (UNII: 2BBL73FIEU)	
<b>BROWN IRON OXIDE</b> (UNII: 1N032N7MFO)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

**Product Characteristics**

<b>Color</b>	brown	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73469-0644-1	4 in 1 CARTON	01/01/2021	
1		1 g in 1 POUCH; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part358F	01/01/2021	

**Labeler** - Scholls Wellness Company LLC (117174744)