

**VISCO-GEL MEDICATED ROUND CALLUS REMOVERS- salicylic acid disc  
PEDIFIX, 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.*

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**Visco-GEL<sup>®</sup> Medicated Round Callus Removers**

***Drug Facts***

**Active Ingredient**

Salicylic acid 40%

**Purpose**

Callus remover

**Uses**

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

**Warnings**

**For external use only Use only as directed**

**Do Not Use**

- if you are diabetic
- on irritated, broken or infected skin
- if you have poor blood circulation

**If discomfort persists, see your doctor or podiatrist.**

**KEEP OUT OF REACH OF CHILDREN.**

If swallowed, get medical help or contact a Poison Control center immediately.

**Directions**

- Wash affected area. Soak in warm water for 5 minutes if desired. Dry thoroughly
- Apply medicated disk directly over callus
- Cover medicated disk with gel pad
- After 48 hours, remove medicated disk
- Repeat procedure every 48 hours as needed (until callus is removed) for up to 14 days

**Other Information**

Store between 59° and 86°F (15° and 30°C)

**Inactive Ingredients**

Polyvinyl Alcohol, Acrylic Copolymer

## **Questions or Comments?**

CALL: 1-800-PEDIFIX (733-4349)

### **PRINCIPAL DISPLAY PANEL - 4 Disk Blister Pack**

**PediFix**®

The Podiatrist's Choice

Since 1885

**NEW!**

**Visco-GEL**®

**Medicated Round**

**Callus Removers**

With Salicylic Acid

**Instant Pain Relief!**

- Safely Removes Calluses
- Adhesive Gel Cushions  
& Protects

**Relief**

**Spot**

**Maximum**

**Strength**

**Washable & Reusable**

**Effective for Weeks**

**4 Medicated Disks**

**4 Cushions**



The Podiatrists' Choice  
Since 1885



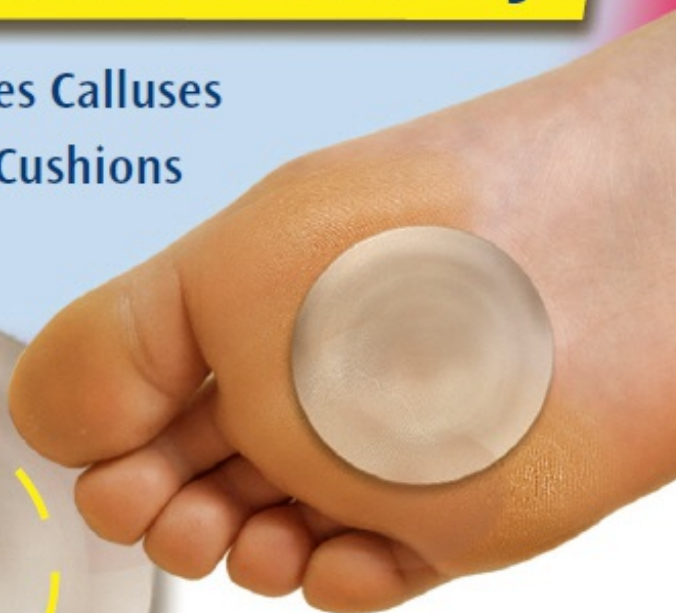
**NEW!**

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With Salicylic Acid

***Instant Pain Relief!***

- Safely Removes Calluses
- Adhesive Gel Cushions & Protects



***Maximum  
Strength***

**Washable & Reusable**  
**Effective for Weeks**

**4** Medicated Disks  
**4** Cushions



The Podiatrists' Choice  
Since 1885



**Visco-GEL® Medicated Round  
Callus Removers cushion and  
protect to relieve pain from calluses, friction and pressure,  
while softening and reducing calluses. Self-sticking pads  
adhere directly to feet or the inside of shoes.**

For a **FREE** *footcare booklet*, more information or a replacement or  
refund call 1-800-PEDIFIX (733-4349), or  
write to PediFix, Inc., 281 Fields Lane,  
Brewster, NY 10509

visit [www.pedifix.com](http://www.pedifix.com)



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**KEEP OUT OF REACH OF CHILDREN.** If swallowed, get medical help or  
contact a Poison Control center immediately.

**Directions**

- Wash affected area. Soak in warm water for 5 minutes if desired.  
Dry thoroughly.
- Remove bandage from backing
- Apply with medicated area directly over callus, cover with gel pad
- After 48 hours, remove medicated bandage
- Repeat procedure every 48 hours as needed (until callus is removed)  
for up to 14 days

**Other Information** Store between 59° and 86°F (15° and 30°C)

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**Item #R819**

REV413

## VISCO-GEL MEDICATED ROUND CALLUS REMOVERS

salicylic acid disc

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68927-0819
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	17.67 mg in 44.18 mg

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68927-0819-1	1 in 1 CONTAINER	06/01/2013	
1		4 in 1 CELLO PACK		
1		44.18 mg in 1 PATCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358F	06/01/2013	

**Labeler** - PEDIFIX, INC. (122271935)

### Establishment

Name	Address	ID/FEI	Business Operations
PEDIFIX, INC.		122271935	label(68927-0819) , pack(68927-0819)

### Establishment

Name	Address	ID/FEI	Business Operations
AKRON		186569323	manufacture(68927-0819)