DR. SCHOLLS INGROWN TOENAIL PAIN RELIEVER- sodium sulfide gel Bayer HealthCare 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.

Dr. Scholls ®

Ingrown Toenail Pain Reliever

Drug Facts

Active ingredient

Sodium sulfide 1%

Purpose

Ingrown toenail reliever

Use

• for temporary relief of pain and discomfort from ingrown to enails

Warnings

For external use only

Do not use on open sores

Ask a doctor before use if you have

- diabetes
- poor blood circulation
- gout

When using this product

- use with a retainer ring
- avoid contact with eyes. If product gets in eyes, flush with water for 15 minutes and get medical help right away.

Stop use and ask a doctor if

- redness or swelling of your toe increases
- discharge is present around the nail
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over:
 - wash affected area and dry thoroughly

- place retainer ring on toe with slot over the area where the ingrown nail and the skin meet. Smooth ring down firmly.
- cut open tip of tube on score mark. Apply enough gel product to fill the slot in the ring. Immediately replace cap on tube.
- place round center section of bandage directly over the gel-filled ring to seal the gel in place. Smooth ends of bandage strip around toe.
- repeat twice daily (morning and night) for up to 7 days until pain and discomfort is relieved or until the nail can be lifted out of the nail groove and easily trimmed
- children under 12 years: ask a doctor

Other information

- save carton for full labeling
- keep tube tightly closed when not in use
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

edetate disodium, hydroxyethyl cellulose, potassium acetate, purified water Distributed by Bayer HealthCare LLC Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - 8.5 g Tube Carton

Dr. Scholl's®

Ingrown

Toenail

PAIN RELIEVER

Sodium Sulfide Gel 1%

Only Treatment Proven to

Relieve Ingrown Toenail Pain*

Medicated gel

softens nail for

easy trimming

NET WT 8.5 g (0.3 OZ)

12 RETAINER RING CUSHIONS

12 PROTECTION BANDAGES



DR. SCHOLLS INGROWN TOENAIL PAIN RELIEVER

sodium sulfide gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-7214
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM SULFIDE (UNII: YGR27ZW0 Y7) (SULFIDE ION - UNII:G15I9 1XETI)	SODIUM SULFIDE	10 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
POTASSIUM ACETATE (UNII: M9 119 11U0 2)		
WATER (UNII: 059QF0KO0R)		

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11523-7214-1	1 in 1 CARTON	05/07/2003	02/28/2021	
1		8.5 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358D	05/07/2003	02/28/2021	

Labeler - Bayer HealthCare LLC. (112117283)

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