WART REMOVER- salicylic acid plaster Pharmaplast SAE

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.

Wart remover plaster

Drug Facts

Active ingredient

Salicylic acid 40% in a plaster vehicle

Purpose

Wart remover adhesive pads

Indications:

- For the removal of common warts. The common wart is easily recognized by the rough 'cauliflower-like' appearance of the surface.
- For the removal of plantar warts on the bottom of the foot.

 The plantar wart is recognized by its location only on the bottom of the foot, its tenderness, and the interruption of the footprint pattern.

Warnings

- For external use only
- Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation.
- If discomfort persists, see your doctor.
- Do not use on moles, birthmarks, warts with hair growing from them, genital warts, or warts on the face or mucous membranes.
- Keep out of reach of children.

Directions

For removal of Common and Plantar warts:

- Wash affected area.
- May soak wart in warm water for 5 minutes.
- Dry area thoroughly.
- Cut plaster to fit wart.
- Apply medicated plaster.
- Repeat procedure every 48 hours as needed (until wart is removed) for up to 12 weeks.

Inactive ingredient

Pressure sensitive adhesive fabric

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Packaging



WART REMOVER salicylic acid plaster Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:28691-0400 Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.4 g		

Inactive Ingredients			
Ingredient Name	Strength		
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
POLYISOBUTYLENE (75000 MW) (UNII: 596C33NS2J)			
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDRO XYPHENYL)PROPIONATE) (UNII: 255PIF62MS)			

I	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:28691- 0400-1	20 in 1 BOX; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	10/07/2016	08/22/2019		
2	NDC:28691- 0400-2	10 in 1 BOX; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	08/22/2019			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358B	10/07/2016	

Labeler - Pharmaplast SAE (644773319)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharmaplast SAE		644773319	manufacture(28691-0400)

Revised: 11/2020 Pharmaplast SAE