WHITE PETROLATUM- white petrolatum ointment
GERITREX 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.

White Petrolatum USP Ointment

Drug Facts

Active Ingredients

White Petrolatum USP 100%

Purpose

Skin Protectant

Uses

- Temporarily protects minor:
- cuts
- scrapes
- burns
- Temporarily protects and helps chapped lips and cracked skin

Warnings

FOR EXTERNAL USE ONLY

Stop use and ask a doctor if:

- condition worsens
- symptoms last for more than 7 days or clear up and occur again within a few days

When using this product: avoid contact with eyes

Don't not use on:

- deep or puncture wounds
- animal bites
- serious burns

In case of deep puncture wounds or severe burns, consult a physician. If irritation, swelling or pain persists, or infection occurs, discontinue use and consult a physician.

Keep out of reach of children.

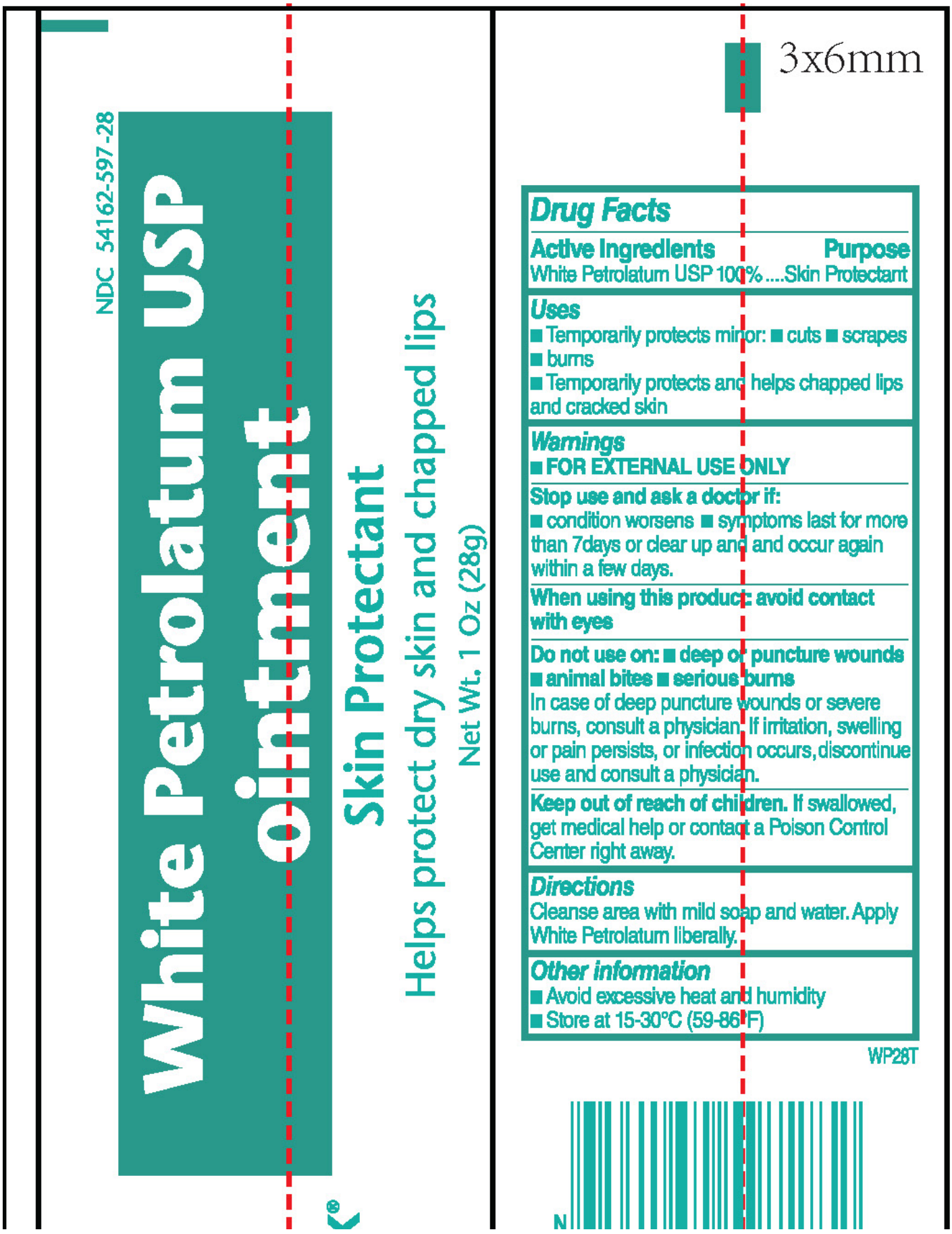
If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Cleanse area with mild soap and water. Apply White Petrolatum liberally.

Other information

- Avoid excessive heat and humidity
- Store at 15-30°C (59-86°F)



WHITE PETROLATUM

white petrolatum ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-597
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	1 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	0.001 g in 1 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54162-597-28	28 g in 1 TUBE; Type 0: Not a Combination Product	09/27/2018	
2	NDC:54162-597-05	5 g in 1 POUCH; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/31/2015	

Labeler - GERITREX LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-597)