

ADVANCED PETROLATUM- petrolatum ointment
Ultra Seal Corporation

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.

Drug Facts

Active Ingredients White Petrolatum 100%

Purpose: Skin Protectant

Temporarily protects minor cuts, scrapes, and burns. Temporarily protects and helps chapped or cracked skin and lips. Helps protect lips from drying effects fo wind and cold weather.

For external use only. Do not use in eyes, on puncture wounds, animal bites, or serious burns or for more than one week unless directed by a doctor..

Stop use and ask a doctor if condition worsens, persists, or recurs.

Keep out of reach of children

Directions: Apply as needed

Inactive Ingredients: None

NDC# 42213-042-05

ADVANCED RELIEF™
THE SCIENCE OF FAST RELIEF.

**WHITE
PETROLATUM**

Skin Protectant

NET WT. 5.0 grams

Ultra Seal Corporation, 521 Main St.
New Paltz, NY 12561 • 845-255-2490

Drug Facts

Active Ingredient	Purpose
(in each gram) White Petrolatum	
100%	Skin Protectant

Uses:

- temporarily protects minor cuts, scrapes and burns
- temporarily protects and helps chapped or cracked skin and lips
- helps protect lips from drying effects of wind and cold weather

Tamper Evident. Do not use if packet is torn, cut or opened.

Drug Facts (continued)

Warnings:

For external use only

Do not use

- in eyes
- on puncture wounds, animal bites or serious burns
- for more than 1 week unless directed by a doctor

Stop use and ask a doctor if

- condition worsens , persists or recurs

Keep out of reach of children.

If ingested, contact a Poison Control Center right away.

Directions:

- apply as needed

ADVANCED PETROLATUM

petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42213-042
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		
MINERAL OIL (UNII: T5L8T28FGP)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42213-042-80	144 in 1 BOX	04/05/2011	
1	NDC:42213-042-05	5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:42213-042-28	28 g in 1 TUBE; Type 0: Not a Combination Product	04/05/2011	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	04/05/2011		

Labeler - Ultra Seal Corporation (085752004)

Registrant - Ultra Seal Corporation (085752004)

Establishment			
Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	pack(42213-042)

Establishment			
Name	Address	ID/FEI	Business Operations
Avatar Corporation		103338687	manufacture(42213-042)

Establishment			
Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		944090448	pack(42213-042)