WHITE PETROLATUM- petrolatum jelly Sion Biotext Medical Ltd

Petrolatum Jelly

Active Ingredient

White Petrolatum (USP, 100% w/w)

Purpose

Skin Protectant

Uses:

- Helps treat and prevent diaper rash
- Helps seal out wetness
- Temporarily protects minor * cuts * scrapes * burns
- Temporarily helps protect and relieve chapped and cracked skin or lips
- Helps prevent and protect chafed skin or minor skin irritations associated with diaper rash
- With each diaper change, especially at bedtime when exposure to wet diapers may be prolonged.

Warnings:

For external use only.

When using this product

• do not get into eyes.

Stop use and ask a doctor if

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

Do not use on

- deep puncture wounds
- animal bites
- serious burns.

Keep out of reach of children.

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

Directions:

• Change wet and soiled diapers promptly.

- Cleanse the diaper area and allow to dry.
- Apply as needed.

Other Information

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

Inactive Ingredients

None

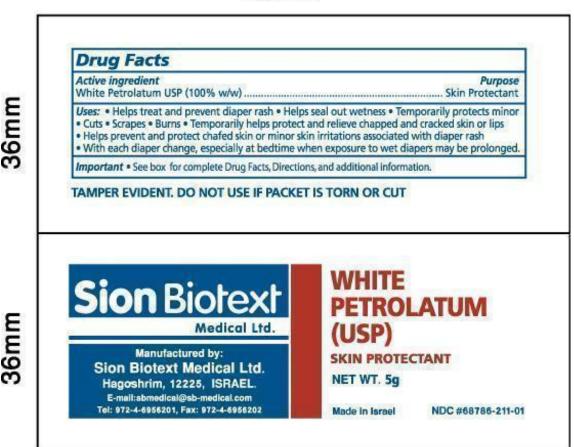
Principal Display Panel

WHITE PETROLATUM (USP)

SKIN PROTECTANT

Made in Israel

88mm



Drug Facts	Drug Facts (continued) 2*6		
Active Ingredient Purpos White Petrolatum (USP, 100% w/w)Skin Protecta			
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 scrapes • burns • Temporarily helps protect and reliev chapped and cracked skin or lips • Helps prevent and protect chafed skin or minor skin irritations associated 	If swallowed, get medical help or contact		
 with diaper rash With each diaper change, especially at bedtime when exposure to wet diapers may be prolonged. 	Directions: • Change wet and soiled diapers promptly. • Cleanse the diaper area and allow to dry. • Apply as needed.		
Warnings: For external use only.	Other information:		
When using this product • do not get into eyes.	Store at 59"- 86"F (15"-30"C) Avoid excessive heat.		
Sion Biotext Medical Ltd.	WHITE PETROLATUM (USP) 3*6 SKIN PROTECTANT		

WHITE PETROLATUM

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petrolatum jelly

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68786-211
Route of Administration	TOPICAL		

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

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68786-211- 01	6 in 1 CASE	02/16/2014	
1		144 in 1 BOX		
1		5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:68786-211- 02	72 in 1 CASE	02/16/2014	
2		1 in 1 BOX		
2		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
	NDC-60706 211			

3	NDC:08/80-211- 03	100 in 1 CASE	02/16/2014	
3		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:68786-211- 04	72 in 1 CASE	02/16/2014	
4		1 in 1 BOX		
4		56.7 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:68786-211- 05	72 in 1 CASE	02/16/2014	
5		1 in 1 BOX		
5		92 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:68786-211- 06	100 in 1 CASE	02/16/2014	
6		92 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:68786-211- 07	6 in 1 CASE	02/16/2014	
7		12 in 1 BOX		
7		113 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:68786-211- 08	100 in 1 CASE	02/16/2014	
8		113 g in 1 TUBE; Type 0: Not a Combination Product		
9	NDC:68786-211- 09	12 in 1 CASE	02/16/2014	
9		425 g in 1 JAR; Type 0: Not a Combination Product		
10	NDC:68786-211- 10	24 in 1 CASE	02/16/2014	
10		284 g in 1 TUBE; Type 0: Not a Combination Product		
Μ	arketing I	nformation		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ОТ	C Monograph Drug	g M016	02/16/2014	

Labeler - Sion Biotext Medical Ltd (532775194)

Registrant - Sion Biotext Medical Ltd (532775194)

Establishment					
Name	Address	ID/FEI	Business Operations		
Sion Biotext Medical Ltd		532775194	manufacture(68786-211)		