

WHITE PETROLATUM- petrolatum jelly
Sion Biotext Medical Ltd

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.

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

Principal Display Panel

WHITE PETROLATUM (USP)

SKIN PROTECTANT

Made in Israel

88mm

36mm

Drug Facts	
Active ingredient	Purpose
White Petrolatum USP (100% w/w)	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.	
Important • See box for complete Drug Facts, Directions, and additional information.	

TAMPER EVIDENT. DO NOT USE IF PACKET IS TORN OR CUT

36mm

 <p>Sion Biotext Medical Ltd.</p>	<p>WHITE PETROLATUM (USP) SKIN PROTECTANT NET WT. 5g</p>
<p>Manufactured by: Sion Biotext Medical Ltd. Hagoshrim, 12225, ISRAEL. E-mail: sbmedical@sb-medical.com Tel: 972-4-6956201, Fax: 972-4-6956202</p>	<p>Made in Israel NDC #68786-211-01</p>

2*6

Drug Facts		Drug Facts (continued)
Active Ingredient White Petrolatum (USP, 100% w/w).....	Purpose Skin Protectant	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.
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.		Do not use on • deep puncture wounds • animal bites • serious burns.
Warnings: For external use only.		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
When using this product • do not get into eyes.		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.

Sion Biotext
Medical Ltd.

Manufactured by:
Sion Biotext Medical Ltd.
Hagshrim, 12225, ISRAEL.
E-mail: sbmedical@sb-medical.com
Tel: 972-4-6956201, Fax: 972-4-6956202

**WHITE
PETROLATUM
(USP)**
SKIN PROTECTANT
NET WT. 1oz (28.35g)

3*6

Made in Israel

NDC # 68786-211-02

3

5

WHITE PETROLATUM

petrolatum jelly

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	1 g in 1 g

Packaging

#	Item 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		
3	NDC:68786-211-03	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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	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)

Revised: 11/2020

Sion Biotext Medical Ltd