

**WHITE PETROLATUM- petrolatum jelly**  
**Sion Biotext Medical Ltd**

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**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

36mm

Drug Facts	
<b>Active ingredient</b> White Petrolatum USP (100% w/w)	<b>Purpose</b> Skin Protectant
<b>Uses:</b> • 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.	
<b>Important</b> • See box for complete Drug Facts, Directions, and additional information.	

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

36mm

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

**Drug Facts**

**Active Ingredient**  
White Petrolatum (USP, 100% w/w).....Skin Protectant

**Purpose**

**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.

**Drug Facts (continued)**

**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.

**Sion Biotext**  
Medical Ltd.

Manufactured by:  
**Sion Biotext Medical Ltd.**  
Hagoshrim, 12225, ISRAEL.  
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**WHITE PETROLATUM (USP)**  
**SKIN PROTECTANT**  
**NET WT. 1oz (28.35g)**

Made in Israel      NDC # 68786-211-02

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		
	NDC:68786-211			

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 Drug	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)