

**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

36mm

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

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

36mm

 <p><b>Sion Biotext</b> Medical Ltd.</p> <p>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</p>	<p><b>WHITE PETROLATUM (USP)</b> <b>SKIN PROTECTANT</b> <b>NET WT. 5g</b></p> <p>Made in Israel      NDC #68786-211-01</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------

2\*6

Drug Facts		Drug Facts (continued)
<b>Active Ingredient</b> White Petrolatum (USP, 100% w/w).....	<b>Purpose</b> Skin Protectant	<b>Stop use and ask a doctor if</b> • condition worsens • symptoms last more than 7 days or clear up and occur again in a few days.
<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>Do not use on</b> • deep puncture wounds • animal bites • serious burns.
<b>Warnings:</b> For external use only.		<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
When using this product • do not get into eyes.		<b>Directions:</b> • Change wet and soiled diapers promptly. • Cleanse the diaper area and allow to dry. • Apply as needed.
		<b>Other information:</b> • 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)**

3\*6

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

5

Made in Israel

NDC # 68786-211-02

3

## WHITE PETROLATUM

petrolatum jelly

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68786-211
<b>Route of Administration</b>	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		
11	NDC:68786-211-11	144 in 1 CASE	12/05/2024	
11		28 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)