

**VITAMIN A D- white petrolatum ointment**  
**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.*

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**Drug Facts**

**Active Ingredient**

White Petrolatum USP (93% 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 help relieve chapped and cracked skin and lips
- Helps prevent and protect from the drying effects of wind and cold weather
- 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**

- The condition persists or gets worse
- Symptoms last more than 7 days or clear up and occur again in a few days

**Do not use on**

- Deep puncture or 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 controlled room temperature 15 °C to 30 °C (59 °- 86 °F)
- Avoid excessive heat and humidity
- Tamper Evident. Do not use if packet is torn, cut or open.

## Inactive Ingredients

Lanolin, Light Liquid Paraffin, Vitamin A, Vitamin D

## Principal Display panel

NDC 68786-213-01

Vitamins A&D Ointment

Intensive Moisturizer for Skin Therapy



For Personal and Professional Use

SION MEDICAL

Made in Israel

144 Packets

Net Wt. 0.17oz(5g)

<p><b>Drug Facts</b></p> <p><b>Active Ingredient (in Each Gram)</b>..... <b>Purpose</b> White Petrolatum, USP, 93% w/w..... Skin Protectant</p> <p><b>Uses</b> • Helps treat and prevent diaper rash • Helps seal out wetness • Temporarily protects minor • Cuts • Scrapes • Burns • Temporarily helps protect and helps relieve chapped and cracked skin or lips • Helps prevent and protect from the drying effects of wind and cold weather • Helps prevent and protect from 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</p> <p><b>Warnings</b> <b>For External Use Only.</b> <b>When using this product</b> • Do not get into eyes <b>Stop use and ask a doctor if</b> • The condition persists or gets worse • Symptoms last more than 7 days or clear up and occur again in a few days <b>Do not use on</b> • Deep or puncture wounds • Animal bites • Serious burns <b>Keep out of reach of children</b> • If swallowed, get medical help or contact a Poison Control Center right away</p> <p><b>Directions</b> Change wet and soiled diapers promptly • Cleanse the diaper area, and allow to dry • Apply as needed</p> <p><b>Other Information</b> • Store at controlled room temperature 15-30° C (59-86° F) • Avoid excessive heat and humidity • Tamper Evident. Do not use if packet is torn, cut or opened</p> <p><b>Inactive Ingredients</b> • Lanolin, Light Liquid Paraffin, Vitamin A, Vitamin D</p>	<p><b>Vitamins A&amp;D Ointment</b> Intensive Moisturizer for Skin Therapy For Personal and Professional Use</p> <p>CE  NDC# 68786-213-01</p> <p>Made in Israel</p>	<p><b>Vitamins A&amp;D Ointment</b> Intensive Moisturizer for Skin Therapy For Personal and Professional Use</p>  <p>SION MEDICAL 144 Packets Net Wt 0.17oz (5g)</p>
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NDC 68786-213-02

Vitamins A&D Ointment

Intensive Moisturizer for Skin Therapy




For Personal and Professional Use

SION MEDICAL

Made in Israel

4 tubes

Net Wt 4 oz (113 g)

<p><b>Vitamins A&amp;D Ointment</b> Intensive Moisturizer for Skin Therapy For Personal and Professional Use</p> <p><b>Drug Facts</b> <b>Active Ingredient (In Each Gram).....Purpose</b> White Petrolatum, USP, 93% w/w.....Skin Protectant</p> <p><b>Uses</b> • Helps treat and prevent diaper rash • Helps seal out wetness • Temporarily protects minor Cuts • Scrapes • Burns • Temporarily helps protect and helps relieve chapped and cracked skin or lips • Helps prevent and protect from the drying effects of wind and cold weather • Helps prevent and protect from 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</p> <p><b>Warnings</b> <b>For External Use Only.</b> <b>When using this product</b> • Do not get into eyes <b>Stop use and ask a doctor if</b> • The condition persists or gets worse • Symptoms last more than 7 days or clear up and occur again in a few days <b>Do not use on</b> • Deep or puncture wounds • Animal bites • Serious burns <b>Keep out of reach of children</b> • If swallowed, get medical help or contact a Poison Control Center right away</p> <p><b>Directions</b> Change wet and soiled diapers promptly • Cleanse the diaper area, and allow to dry • Apply as needed</p> <p><b>Other Information</b> • Store at controlled room temperature 15°-30° C (59°-86° F) • Avoid excessive heat and humidity • Tamper Evident. Do not use if packet is torn, cut or opened</p> <p><b>Inactive Ingredients</b> • Lanolin, Light Liquid Paraffin, Vitamin A, Vitamin D</p> <p><small>Sion Medical Ltd., Hagothrim, 1222500, ISRAEL Email: sales@ion-medical.com Tel: +972-4-6996201 www.ion-medical.com E.A.P. - Objele s.r.l. Bd Generali Vialto 53, 1030 Brussafero, BELGIUM Email: ms@obje.com Tel: +32(2) 73249604 www.obje.com</small></p>	<p><b>Vitamins A&amp;D Ointment</b> Intensive Moisturizer for Skin Therapy</p>  <p>For Personal and Professional Use</p> <p>Made in Israel</p> <p>CE </p> <p>NDC# 68786-213-02</p>	<p><b>Vitamins A&amp;D Ointment</b> Intensive Moisturizer for Skin Therapy</p>  <p>For Personal and Professional Use</p> <p>4 Tubes Net Wt 4oz (113g) SION MEDICAL</p>	<p><b>Vitamins A&amp;D Ointment</b> Intensive Moisturizer for Skin Therapy</p>  <p>For Personal and Professional Use</p>  <p>7 290100 666098</p> <p>Made in Israel</p> <p>CE </p> <p>NDC# 68786-213-02</p>
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## VITAMIN A D

white petrolatum ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68786-213
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	0.93 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
VITAMIN A (UNII: 81G40H8B0T)	
VITAMIN D (UNII: 9VU1KI44GP)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68786-213-01	6 in 1 CASE	02/14/2017	
1		144 in 1 BOX		
1		5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:68786-213-02	18 in 1 CASE	02/14/2017	
2		4 in 1 BOX		
2		113 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:68786-213-03	6 in 1 CASE	01/31/2019	
3		12 in 1 BOX		
3		113 g in 1 PACKET; 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	02/14/2017	

**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(68786-213)

Revised: 1/2022

Sion Biotext Medical Ltd.