

## **VITAMINS A AND D WITHOUT LANOLIN- 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(in Each Gram)**

White Petrolatum, USP, 93% w/w

#### **Purpose**

Skin Protectant

#### **Uses**

- Temporarily protects minor
- Cuts
- Scrapes
- Burns
  
- Temporarily helps protect and helps relieve chapped and cracked skin or lips
- Helps prevent and protect from drying effects of wind and cold weather
- Temporarily protects and helps relieve minor skin irritation and itching due to:
  - Rashes
  - Eczema

#### **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 or 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**

- Apply as needed

### **Other Information**

- 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

### **Inactive Ingredients**

- Lavender Oil, Light Liquid Paraffin, Vitamin A, Vitamin D

### **Principal Display Panel**

NDC 68786-411-01

Made In Israel

144 Packets

SionBiotext Medical Ltd.

For Professional and Hospital Use





Vitamin A and D

Ointment

without Lanolin

Ref.: 54J811-5201-000

Net Wt 5 gram

144 Sion Biotext	144 Sion Biotext
<b>Packets Medical Ltd.</b> <b>Drug Facts</b> <b>Active Ingredient (in Each Gram)</b> Purpose White Petrolatum, USP 93% w/w ... Skin Protector <b>Uses</b> • 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 • Temporarily protects and helps relieve minor skin irritations and itching due to: • Rashes • Eczema <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 <b>Directions</b> • Apply as needed <b>Other Information</b> • Store at controlled room temperature 15-30° C (59-86° F) • Avoid excessive heat and humidity • Keep out of reach of children • Do not use if packet is torn, cut or opened <b>Inactive Ingredients</b> • Lavender Oil, Light Liquid Paraffin, Vitamin A, Vitamin D  NDC # 68786-411-01      Made in Israel	<b>Packets Medical Ltd.</b> <b>For Professional and Hospital Use</b> <b>Vitamins A&amp;D Ointment</b> without Lanolin  NDC # 68786-411-01      Made in Israel
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## VITAMINS A AND D WITHOUT LANOLIN

white petrolatum ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68786-411
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	93 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
VITAMIN A (UNII: 81G40H8B0T)	
VITAMIN D (UNII: 9VU1KI44GP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68786-411-01	6 in 1 CASE	02/11/2016	
1		144 in 1 BOX		
1		5 g in 1 PACKET; Type 0: Not a Combination Product		

### Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	part346	01/07/2016	

**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(68786-411)

Revised: 12/2022

Sion Biotext Medical Ltd