

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.

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 |
|---|---|--|---|
| Packets | Medical Ltd. | Packets | Medical Ltd. |
| Drug Facts Active Ingredient (in Each Gram) Purpose White Petrolatum, USP 93% w/w ... Skin Protector Uses • 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: • Rash • 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 • Keep container tightly closed. Do not use if packet is torn, cut or opened Inactive Ingredients • Lavender Oil, Light Liquid Paraffin, Vitamin A, Vitamin D | Vitamins A&D Ointment <i>without Lanolin</i>  726010065534 NDC # 68786-411-01 Made in Israel | For Professional and Hospital Use Vitamins A&D Ointment <i>without Lanolin</i>  726010065534 Ref.: 54J811-5201-000 Net Wt 5 grams NDC # 68786-411-01 Made in Israel | Vitamins A&D Ointment <i>without Lanolin</i>  726010065534 NDC # 68786-411-01 Made in Israel |
|  Sion Biotext Medical Ltd. Hagdarem, 122200, ISRAEL. Email: sales@sion-medical.com Tel: +972-4-6090201 www.sion-medical.com E.A.R. - Obelix s.a. Bd Général Waels 53, 1030 Brussels, BELGIUM. Email: mail@obelix.net Tel: +32(0)2-732-50-54 www.obelix.net | 144 Packets |  Sion Biotext Medical Ltd. Hagdarem, 122200, ISRAEL. Email: sales@sion-medical.com Tel: +972-4-6090201 www.sion-medical.com E.A.R. - Obelix s.a. Bd Général Waels 53, 1030 Brussels, BELGIUM. Email: mail@obelix.net Tel: +32(0)2-732-50-54 www.obelix.net | 144 Packets |

VITAMINS A AND D WITHOUT LANOLIN

white petrolatum ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68786-411 |
| Route of Administration | 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: 1/2022

Sion Biotext Medical Ltd