

PETROLATUM JELLY- petrolatum jelly
ASTONEA LABS PRIVATE LIMITED

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.

ASTONEA 99.9%

Active Ingredient

White Petrolatum (99.9% w/w)

Purpose

Skin Protectant

Uses

- temporarily protects minor cuts, scrapes, burns and sunburn
- temporarily protects and helps relieve chapped or cracked skin
- helps protect from drying effect of wind and cold weather
- helps treat and prevent diaper rash
- help seal out wetness

Warnings

FOR EXTERNAL USE ONLY

When using this product

- do not get into the eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last for more than 7 days or clean 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

Inactive Ingredient

Fragrance

Package Label



Drug Facts		When using this product
Active ingredient White Petrolatum (99.9%)	Purpose Skin Protectant	do not get into eyes
Uses ■ temporarily protects minor cuts, scrapes, burns and sunburn ■ temporarily protects and helps relieve chapped or cracked skin ■ helps protect from the drying effects of wind and cold weather ■ helps treat and prevent diaper rash ■ helps seal out wetness		Stop use and ask a doctor if ■ condition worsens ■ symptoms last more than 7 days or clean up and occur again in a few days
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Manufactured for:
Astonea Labs Private Limited
Village Haripur, Tehsil Raipurani,
Near Mouli Police Station, Panchkula, Haryana,
India - 134204 | Made in India

HR/DRUGS 1105-OSP(H)



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PETROLATUM JELLY

petrolatum jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	99.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-101-03	226 g in 1 JAR; Type 0: Not a Combination Product	01/01/2023	
2	NDC:77338-101-05	368 g in 1 JAR; Type 0: Not a Combination Product	01/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/11/2016	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 1/2023

ASTONEA LABS PRIVATE LIMITED