WAX SPF 50- zinc oxide, allantoin ointment
Biomin LLC.

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.

Wax + SPF 50

DRUG FACTS

Active Ingredients

Zinc Oxide 20.00%

Allantoin 2%

Purpose

Sunscreen

Skin Protectant

Uses:

Temporarily protects and helps relieve chapped or chafed skin. Helps prevent and protect from the drying effects of wind and cold weather. Helps prevent sunburn. Higher SPF gives more sunburn protection.

Warnings:

For external use only.

Do not use
- on damaged or broken skin.
- Do not use deep or puncture wounds animal bites serious burns.

Stop use and ask a doctor
- If rash occurs conditions worsens symptoms last more than 7 days or clear up again within a few days.

When using this product
- Keep out of eyes.
- Rinse with water to remove.

Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Apply liberally 15 minutes before sun exposure and as needed. Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every two hours.
- Children under 6 months of age: Ask a doctor.

Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10 am - 2 pm. Wear long-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients:

Simmondsia Chinensis (Jojoba) Seed Oil, Jojoba Esters, Caprylic/Capric Triglyceride, Polyhydroxystearic Acid, Argania Spinosa Kernel Oil (Argan Oil), Tocopherol, Bisabolol, Calcium Silicate, Phytosteryl/Behenyl/Octyldodecyl Lauroyl Glutamate, Oryza Sativa (Rice) Bran Oil, Oryza Sativa (Rice) Bran Wax, Rhus Succedanea Fruit Wax, Helianthus Annuus (Sunflower) Seed Oil

Other Information:

Protect this product from excessive heat and direct sun.

Package Labeling:

WAX SPF 50
zinc oxide, allantoin ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82177-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	200 mg in 1 mL
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
JOJOBA OIL (UNII: 724GKU717M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ARGAN OIL (UNII: 4V59G5UW9X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LEVOMENOL (UNII: 24WE03BX2T)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
RICE BRAN OIL (UNII: LZO6K1506A)	
RICE BRAN (UNII: R60QEP13IC)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82177-002-00	60 mL in 1 JAR; Type 0: Not a Combination Product	07/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/01/2022	

Labeler - Biomin LLC. (105075828)

Revised: 6/2022 Biomin LLC.