

4SPORT SKINCARE ANTI CHAFING- lanolin lotion

4sport D.o.o.

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.

4sport skincare anti chafing lotion

DRUG FACTS

Active ingredient:

Lanolin 40%

Purpose

Skin protectant

Uses:

Temporarily protects the skin and prevents chafing, blisters and irritation.

Warnings:

- For external use only. Do not use on: deep or puncture wounds, animal bites, serious burns
- When using this product: use only as directed, avoid contact with eyes or mucous membrane

Stop use and ask a doctor if:

- Redness occurs, irritation develops, symptoms persist for more than 7 days, or clear up and occur again within a few days
- If pregnant or breast-feeding ask a health professional before use.
- Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Direction:

Apply to intact skin before any chafing and blister causing activity. Wash off with mild soap.

Inactive ingredients:

Prunus Dulcis (Sweet Almond) Oil, Mineral Oil, Vitis Vinifera (Grape) Seed Oil, Prunus Armeniaca (Apricot) Seed Oil, Retinyl Palmitate, Linoleic Acid, Parfum/Fragrance, Lavandula Angustifolia (Lavender) Essential oil, Limonene, Linalool

protects and nurtures your skin

The very best from nature

Made with the best ingredients to protect your skin from chafing, blisters and irritation.

No chafing

No blisters

No irritation

No petroleum

No parabens

No alcohol

Manufactured in EU for:

4SPORT Ltd.,

Ulica Mirka Vadnova 19,

4000 Kranj, Slovenia

www.4sport-skincare.com

Our anti chafing lotion forms a breathable moisture barrier on the skin, to help fight friction. The formulation makes it easy to apply for all-day protection from skin on skin rubbing, chafing from clothing, friction from shoes, protective gear, and other irritants.

- Sweat and water resistant
- Whole body use
- Non-irritating
- Airless ecosolution pump bottle container

Better safe than sorry!

Packaging

INNER LABEL



OUTER LABEL



DRUG FACTS PANEL

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4SPORT SKINCARE ANTI CHAFING

lanolin lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71289-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII:7EV65EAW6H)	LANOLIN	40 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALMOND OIL (UNII: 66YXD4DKO9)	
MINERAL OIL (UNII: T5L8T28FGP)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71289-101-02	1 in 1 BOX	01/07/2018	
1		100 mL in 1 BOTTLE, DISPENSING; 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	01/07/2018	

Labeler - 4sport D.o.o. (644105806)

Revised: 6/2018

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