

THE SKATEBOARDING PAIN RELIEVING LINIMENT- menthol cream

The Cream Skateboarding Liniment Pty 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.

The Cream Skateboarding Pain Relieving Liniment

Drug Facts

Active ingredient

Menthol 13%

Purpose

External Analgesic

Use

- For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, strains, bruises, and sprains.

Warnings

For external use only

When using this product

- use only as directed
- avoid contact with the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact Poison Control Center right away.

Directions

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: Consult a doctor.

Other information

- Store below 86°F / 30°C

Inactive ingredients

arnica oil, camellia (Camellia olifera) oil, cetareth 20, cetaryl alcohol, coconut (Cocos nucifera) oil, comfrey extract, diazolidinyl urea, glycerin, iodopropynyl butylcarbamate, propylene glycol, shea

(Butyrospermum parkii) nut butter, tocopherols, vanilla fragrance, water (aqua)

Package Labeling:



<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days <p>Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. ■ Children under 2 years of age: Consult a doctor. <p>Other information</p> <ul style="list-style-type: none"> ■ Store below 86°F / 30°C 	<p>Drug Facts (continued)</p> <p>Inactive ingredients</p> <p>arnica oil, camellia (Camellia oilifera) oil, ceteareth 20, cetearyl alcohol, coconut (Cocos nucifera) oil, comfrey extract, diazolidinyl urea, glycerin, iodopropynyl butylcarbamate, propylene glycol, shea (Butyrospermum parkii) nut butter, tocopherols, vanilla fragrance, water (aqua)</p>
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THE SKATEBOARDING PAIN RELIEVING LINIMENT

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72045-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	130 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CAMELLIA OIL (UNII: T1PE06G0VE)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCERIN (UNII: PDC6A3C0OX)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72045-000-00	40 g in 1 TUBE; Type 0: Not a Combination Product	01/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/17/2018	

Labeler - The Cream Skateboarding Liniment Pty Ltd (744854942)

Revised: 1/2018

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