

RESTORAL- menthol ointment
Natures Formulae Health Products 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.

Restoral

Active Ingredient

Menthol 0.2%

Purpose

Topical analgesic

Uses

For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, or minor skin irritations

Warnings

For external use only

Flammable - keep away from fire or flame

Use may result in increased topical anti-inflammatory effects of steroids, due to presence of marshmallow herb

When using this product

Avoid contact with eyes and mucous membranes; if this happens, rinse with vegetable oil

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

Do not use

On wounds or damaged skin

If allergic to marshmallow root or chickweed

if pregnant or breast-feeding

ask a health professional before use

keep out of reach of children

if product is swallowed, get medical help or contact a Poison Control Centre right away

Directions

Adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily.

Not recommended for children under 12 years of age.

Inactive ingredients

Agrimonia eupatoria leaf extract, althaea officinalis root extract, beeswax (yellow), berberis aquifolium extract, calendula officinalis flower, chamomilla recutita (matricaria) flower extract, eucalyptus oil, larrea tridentata extract, lobelia inflata extract (lobelia), melaleuca alternifolia (tea tree) leaf oil, olive oil, peppermint oil, propolis extract, quercus alba bark extract, rosmarinus officinalis (rosemary) leaf extract, St. John's wort, stellaria media (chickweed) extract, symphytum officinalis leaf extract, trifolium pratense (clover) flower extract and witch hazel

Questions?

1-877-275-7253

Principle Display Panel information

Restoral

topical analgesic ointment

net wt. 54.1g (1.91oz) and net wt. 13.5g (0.47oz)

Restoral Topical analgesic ointment - Outer label





7.5 CM

**FLAP
OUTER FACING**

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING KEEP THIS PACKAGE FOR FULL INFORMATION.

Drug Facts

Active ingredient	Purpose
Menthol 0.2%	Topical analgesic

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DO NOT USE IF SECURITY SEAL AROUND TIN IS BROKEN OR MISSING.

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1
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2

Drug Facts (continued)

Warnings
For external use only.
Flammable: Keep away from fire or flame.
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When using this product, avoid contact with the eyes and mucous membranes; if this happens, rinse with vegetable oil.
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Drug Facts (continued)

Use may result in increased topical anti-inflammatory effects of steroids, due to presence of marshmallow herb.
If pregnant or breast-feeding, ask a health professional before use.
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3

4

Drug Facts (continued)

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Other information Store at room temperature.	
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Questions? 1-877-275-7253	

RESTORAL

menthol ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69204-023

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
COMFREY ROOT (UNII: M9VVZ08EKQ)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ST. JOHN'S WORT (UNII: UFH8805FKA)	
STELLARIA MEDIA (UNII: 2H03479QVR)	
TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
LARREA TRIDENTATA LEAF (UNII: PK0TXD049P)	
BERBERIS AQUIFOLIUM ROOT (UNII: 746TB9VNDP)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
TEA TREE OIL (UNII: VIF565UC2G)	
AGRIMONIA EUPATORIA LEAF (UNII: 8Z160YZ4AP)	
QUERCUS ALBA BARK (UNII: 93LP7Y8EGT)	
ROSEMARY (UNII: IJ67X351P9)	
WITCH HAZEL (UNII: 101I4J0U34)	
MATRICARIA CHAMOMILLA FLOWERING TOP (UNII: 3VNC7T6Z02)	
LOBELIA INFLATA LEAF (UNII: 7QFT17RLRG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69204-023-01	1 in 1 BOX	09/12/2018	
1		54.1 g in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:69204-023-02	13.5 g in 1 CONTAINER; Type 0: Not a Combination Product	09/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/12/2018	

Establishment

Name	Address	ID/FEI	Business Operations
Natures Formulae Health Products Ltd.		241385587	manufacture(69204-023)

Revised: 10/2016

Natures Formulae Health Products Ltd.