

## **OSTEO BI-FLEX ROLL-ON EXTRA STRENGTH- menthol cream**

**The Nature's Bounty Company**

*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.*

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### **Active ingredients**

Menthol 8% .....Topical analgesic

### **Purpose**

Purpose: Topical analgesic

### **Uses**

For the temporary relief of minor aches and pains of muscles and joints associated with: ●arthritis ●simple backache ●strains ●bruises ●sprains

Warnings: For external use only.

Flammable: Keep away from fire or flame. Store at room temperature.

### **When using this product**

- Use only as directed
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds or damaged, broken or irritated skin
- Do not bandage tightly or apply local heat (such as heating patches) to the area of use.

### **Discontinue use and consult a doctor if**

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Irritation develops/excessive irritation occurs
- Redness is present

### **If pregnant or breastfeeding**

If pregnant or breastfeeding, ask a health care professional before use.

### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center immediately.

### **Directions:**

Directions: adults and children over 12 years: Roll directly onto affected area without the need to rub,

massage or bandage. Repeat if necessary, but not more than 4 times daily.

## Directions

Directions: adults and children over 12 years: Roll directly onto affected area without the need to rub, massage or bandage. Repeat if necessary, but not more than 4 times daily. •Children 12 years of age or younger: consult a doctor.

## Inactive ingredients:

Inactive ingredients: boswellia serrata extract, carbomer, dimethylsulfone (MSM), eucalyptus oil, glucosamine sulfate, glycerin, peppermint oil, SD alcohol 39c, triethanolamine, water.

## Questions?

Call 1-888-VITAHELP (848-2435)

**2X** THE ACTIVE INGREDIENT AS BIOFREEZE<sup>®</sup> ROLL-ON<sup>\*</sup>

**NEW!**

**Osteo Bi-Flex<sup>®</sup>**

JOINT HEALTH

FOR ARTHRITIS, JOINTS & MUSCLES

**EXTRA STRENGTH**

WITH **DRY TOUCH TECHNOLOGY**  
NON-STICKY, NO RESIDUE, NO MESS

3 oz. (82 g)

**Drug Facts**

**Active ingredients**  
Menthol 8% .....

**Uses** For the temporary relief of minor aches and pains in the muscles and joints associated with: •arthritis •bruises •sprains **Warnings:** For external use only. Keep away from fire or flame. Store at room temperature. Do not use on broken or irritated skin. Do not apply to eyes, nose, mouth, or mucous membranes. Do not use on children under 12 years of age. Do not use if you are pregnant or breastfeeding, ask a health care professional for advice. Do not use if you have a known allergy to any of the ingredients. If you experience severe irritation or allergic reaction, discontinue use and consult a doctor. If condition worsens or does not improve after 7 days of use, or if you experience excessive irritation, discontinue use and consult a doctor. If swallowed, get medical help or contact Poison Control Center immediately. **Directions:** For adults and children over 12 years: Roll directly onto affected area without the need to rub, massage or bandage. Repeat if necessary, but not more than 4 times daily. •Children 12 years of age or younger: consult a doctor. **Inactive ingredients:** boswellia serrata extract, carbomer, dimethylsulfone (MSM), eucalyptus oil, glycerin, peppermint oil, SD alcohol 39c, triethanolamine, water. **Questions?** call 1-888-VITAHELP (848-2435)

\*Biofreeze Classic Pain Relieving Roll-On, 2.5 oz. contains 4% menthol.

MANUFACTURED FOR:  
REXALL SUNDOWN, INC.,  
BOCA RATON, FL 33487 USA

848-2435

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Osteo BiFlex

Joint Health

PAIN RELIEVING

ROLL-ON FOR ARTHRITIS, JOINTS & MUSCLES

With DRY TOUCH TECHNOLOGY NON-STICKY, NO RESIDUE, NO MESS

## OSTEO BI-FLEX ROLL-ON EXTRA STRENGTH

menthol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24737-1901	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	8 g in 100 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
ALCOHOL (UNII: 3K9958V90M)		54 g in 100 g		
WATER (UNII: 059QF0KO0R)		29.5 g in 100 g		
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:24737-1901-3	82 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/01/2019	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part341	03/31/2019		

**Labeler** - The Nature's Bounty Company (052790318)

Revised: 12/2018

The Nature's Bounty Company