

**MYOFLEX- trolamine salicylate cream**  
**Dr. Reddy's Laboratories Inc.**

*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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**Myoflex®**

**Drug Facts**

**Active ingredient**

Trolamine salicylate 10%

**Purpose**

Pain relieving cream

**Use**

- temporarily relieves minor aches and pains of muscles and joints due to arthritis, strains and sprains, and simple backache

**Warnings**

**For external use only**

**Do not use**

- in or near eyes
- on wounds or damaged skin

**Stop use and ask a doctor if**

- condition lasts or gets worse
- symptoms last more than 7 days or clear up and occur again within a few days

**If you are pregnant or breast-feeding**, ask a health care professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

**Directions**

- do not use more than directed
- adults and children 2 years and older
  - apply to affected area not more than three to four times a day
  - may be covered with a sterile bandage
- children under 2 years: ask a doctor

**Other information**

- store at controlled room temperature 20-25°C (68-77°F)
- close cap tightly

**Inactive ingredients**

aloe vera gel, cetyl alcohol, glycerin, DMDM hydantoin, methylparaben, propylparaben, mineral oil, stearic acid, triethanolamine, purified water

**Questions?**

call **1-800-790-6417**

**PRINCIPAL DISPLAY PANEL - 113 g Tube Box**

NDC 55741-304-04

***up to 8 - Hour Formula***

***MYOFLEX<sup>®</sup>***

***PAIN RELIEVING CREAM***

***TROLAMINE SALICYLATE 10%***

***Targeted Relief From Minor Backache, Arthritis, Muscle & Joint Pain***

***□ Deep Penetrating   □ Odorless   □ Pharmacist Recommended***

**NET WT. 4 oz (113 g)**

up to **8-Hour Formula**

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GLUE



trolamine salicylate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55741-304
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Trolamine salicylate</b> (UNII: H8O404BHD) (Salicylic Acid - UNII:O414PZ4LPZ)	Trolamine salicylate	10 g in 100 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>aloe vera leaf</b> (UNII: ZY81Z83H0X)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>DMDM hydantoin</b> (UNII: BYR0546TOW)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>mineral oil</b> (UNII: T5L8T28FGP)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
<b>trolamine</b> (UNII: 9O3K93S3TK)	
<b>water</b> (UNII: 059QF0KO0R)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55741-304-04	1 in 1 BOX	05/24/2016	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	05/24/2016	

**Labeler** - Dr. Reddy's Laboratories Inc. (802315887)

Revised: 6/2016

Dr. Reddy's Laboratories Inc.