FLEXALL PAIN RELIEVING- menthol gel
Rebel Distributors Corp

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.

Flexall Max

Drug Facts

Active ingredient

Menthol 16%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

Warnings

For external use only

Allergy alert:

do not use

if you are allergic to salicylates (including aspirin) unless directed by a doctor.

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged, broken or irritated skin

Stop use and ask a doctor if

- condition worsens
- redness is present
- 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 right away.

Directions

adults and children over 12 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 3 to 4 times daily

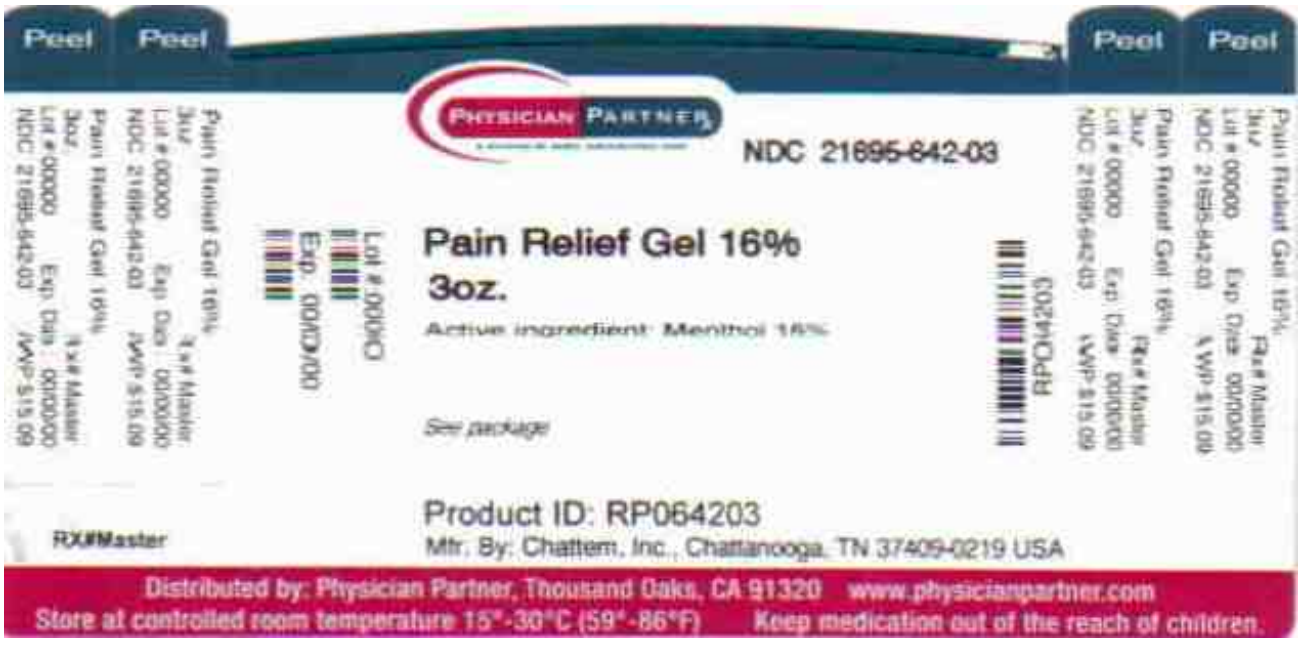
children 12 years or younger: ask a doctor

Inactive ingredients

allantoin, aloe barbadensis leaf juice, carbomer, diisopropyl adipate, eucalyptus globulus leaf oil, glycerin, mentha piperita (peppermint) oil, methyl salicylate, SD alcohol 40 (15% w/w), steareth-2, steareth-21, thymus vulgaris (thyme) oil, tocopheryl acetate, triethanolamine, water (234-166)

PRINCIPAL DISPLAY PANEL

Maximum Strength
Flexall®
Pain Relieving Gel In An Aloe Vera Base
Menthol 16%
Net wt 3 oz (85 g)



FLEXALL PAIN RELIEVING

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21695-642(NDC:41167-1602)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.16 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
THYME OIL (UNII: 2UK410MY6B)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:21695-642-03	1 in 1 CARTON		
1		85 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/1997	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011 Rebel Distributors Corp