MUSCULAR BALM- capsaicin menthol methyl salicylate ointment Borden Company (Private) Limited

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.

Drug Facts

Active Ingredients

Capsaicin 0.15% Menthol 13.5% Methyl Salicylate 30%

Purpose

External Analgesic External Analgesic External Analgesic

Use

For the temporary relief of minor pains and aches of muscles and joints associated with \blacksquare simple backache \blacksquare arthritis \blacksquare strains

■ bruises ■sprains

Warnings

- For external use only
- Avoid getting into the eyes or on mucous membranes.

When using this product

■ do not apply to wounds or damaged skin ■ do not bandage tightly ■ do not use if excessive irritation of the skin develops

■ do not use otherwise than as directed

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 ■ pain persists for more than 10 days ■ redness is present ■ conditions affect children under 12 years of age.

Keep out of reach of children

to avoid accidental poisoning. In case of accidental ingestion, contact a doctor or Poison Control Center Immediately

Directions

- Adults and children 12 years of age and over: Apply to affected area not more than 3 to 4 time daily.
- Children under 12 years of age:consult a doctor

Inactive Ingredients

eucalyptol, fragrance, paraffin wax and petroleum jelly

Package Label



MUSCULAR B							
capsaicin menthol me	thyl salicylate	eointment					
Product Informat	ion						
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:43405-007		
Route of Administrat	oute of Administration TOPICAL						
Active Inque dient	Active Mai						
Active Ingredient/Active Moiety							<u> </u>
Ingredient Name					Basis of Strength		Strength
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)					CAPSAICIN		0.15 g in 100 g
					MENTHOL METHYL SALICYLATE		13.5 g in 100 g 30 g in 100 g
Inactive Ingredie	nts						
Ingredient Name						Strength	
EUCALYPTOL (UNII: F	V6J6604TK)						
PARAFFIN (UNII: 1900)	E3H2ZE)						
PETROLATUM (UNII: 4	T6H12BN9U)						
Packaging # Item Code	1	Package Description	Marketing Start Da			ate Marketing End Date	
	1 in 1 BOX		05/14/2010				ting Life Date
	THITDOA						
1 NDC:43405-007-01	20 g in 1 JAR;	Type 0: Not a Combination Produc	t				
Item Code 1 NDC:43405-007-01 1 NDC:43405-007-20	20 g in 1 JAR;	Type 0: Not a Combination Produc	2t				
 NDC:43405-007-01 NDC:43405-007-20 		Type 0: Not a Combination Produc	2t				
1 NDC:43405-007-01	rmation	Type 0: Not a Combination Produc		Market	ing Start 1	Date Mark	eting End Date

Labeler - Borden Company (Private) Limited (595109711)

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Borden Company (Private) Limited