

**AMRUTANJAN RELIEF STRONG PAIN BALM- menthol, methyl salicylate ointment**  
**AMRUTANJAN HEALTH CARE 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.*

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**Active ingredients**

Menthol 15.0%

Methyl Salicylate 15%

**Purpose**

Menthol                    Topical analgesic

Methyl Salicylate      Topical analgesic

**Uses**

- Temporarily relieves pain associated with headache, cold, body ache and nasal congestion
- Provides temporary relief of minor pains of muscles and joints

**Warnings**

For External use only

- Avoid contact with eyes
- Do not use otherwise than as directed

**When using this product**

- Do not heat
- Do not microwave
- Do not use near an open flame
- Do not add to hot water or any container where heating water. May cause splattering and result in burns
- Avoid contact with wounds, mucous membranes, broken or irritated skin
- Do not bandage tightly or use with heating pad

**Stop use of this product and consult a doctor if**

- Condition worsens
- Redness or irritation develops
- Symptoms persist for more than 7 days or clear up and occur again within a few days or is accompanied by fever, rash, or persistent headaches

**If pregnant or breast-feeding, or if you have sensitive skin, ask a healthcare personal before use**

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

**Directions**

- See important warning "When using this product"
- Adults and children over 12 years
- Apply and gently massage over the affected area
- Repeat 2- 3 times daily, or as directed by a doctor
- Children 12 years or younger: ask a doctor

### **Other Information**

Store at room temperature

### **Inactive ingredients**

butylated hydroxy toluene, cetostreayl alcohol, microcrystalline wax, paraffin, petrolatum

### **Questions?**

Call 1-888-611-6811

**NDC 53554-020-05**

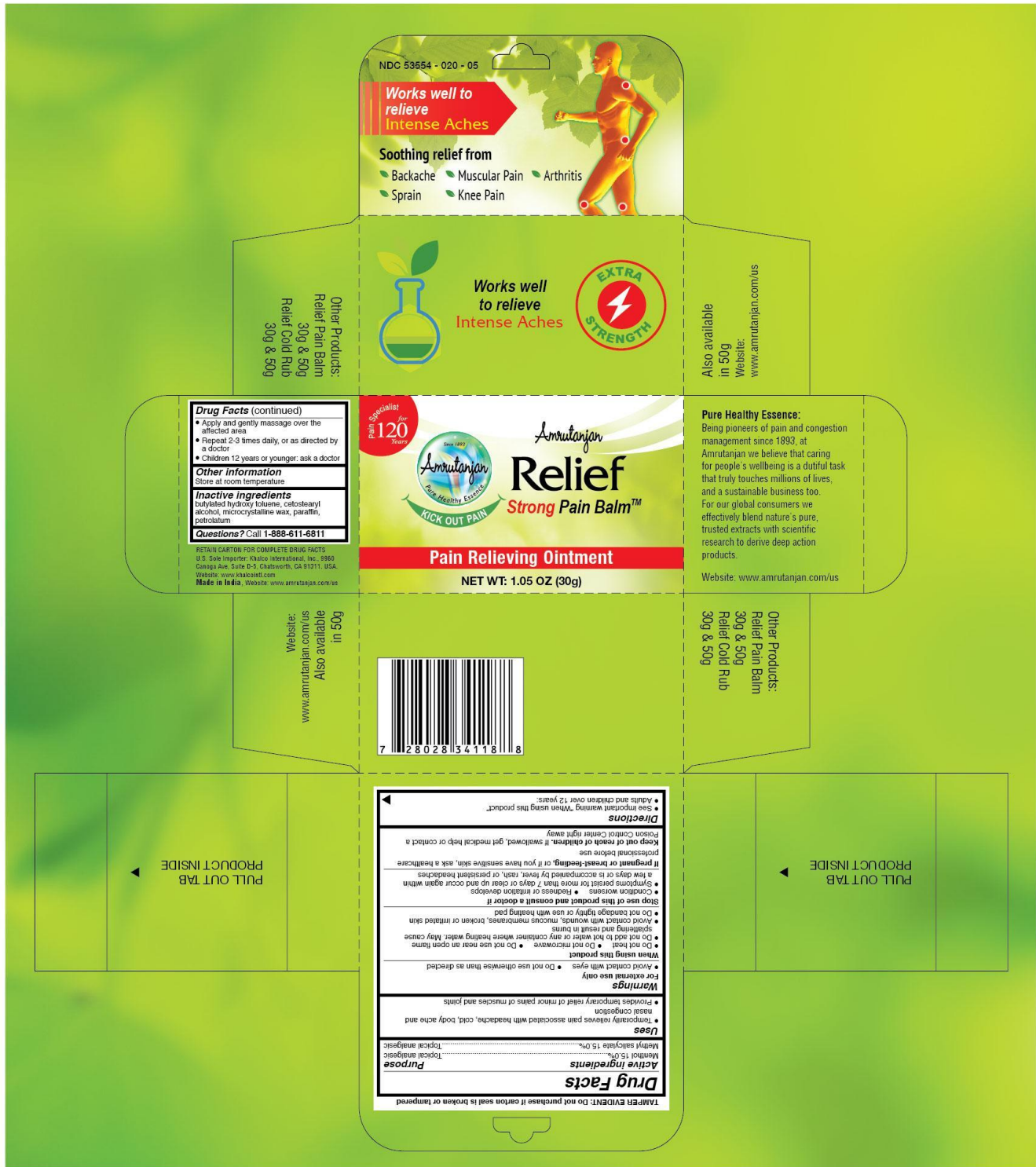
**AMRUTANJAN**

**RELIEF Strong PAIN BALM™**

**PAIN RELIEVING OINTMENT**

**NET WT: 1.05 OZ (30g)**

PRINCIPAL DISPLAY PANEL - 30 g Jar Carton



A4687 Amrutanjan 30g Strong Pain Balm Green CB New KLD 04 08 15

## AMRUTANJAN RELIEF STRONG PAIN BALM

menthol, methyl salicylate ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53554-020
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.15 g in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.15 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	

**Product Characteristics**

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53554-020-05	1 in 1 CARTON	08/12/2015	
1		30 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:53554-020-10	1 in 1 CARTON	08/12/2015	
2		50 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:53554-020-03	1 in 1 BLISTER PACK	08/12/2015	
3		9 g in 1 JAR; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/23/2015	

**Labeler** - AMRUT ANJAN HEALTH CARE LIMITED (650128309)**Registrant** - AMRUT ANJAN HEALTH CARE LIMITED (650128309)**Establishment**

Name	Address	ID/FEI	Business Operations
MAKSON INDUSTRIES PRIVATE LIMITED		650553980	manufacture(53554-020)

