PAIN GOODBYE MEDICATED CREAM- menthol 5% cream Austin Biotechnology 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.

PAIN GOODBYE MEDICATED CREAM

ACTIVE INGREDIENTS

Menthol 5%

PURPOSE

Menthol External Analgesic

USES

Uses for the temporary relief of minor aches, and points of muscles and joints associated with simple backache, arthritis and strains.

WARNINGS

Use only as directed. For External Use Only. Avoid contact with eyes, mucous membrances, rashes, wounds or damaged skin. Package not child resistent, in case of accidental ingestion, contact doctor immediately.

WARNINGS

Keep out of reach of children.

WARNINGS

Do not apply on nose and genital area. If rashes, redness and itchness result, discontinue use and consult a doctor.

WARNINGS

If prone to allergic reaction to the product, consult a doctor before using.

DIRECTION

Adult and children 12 years of age and older; apply a few drops to affected area and rub gently 3 to 4 times daily. Children under age of 12, do not use, consult a doctor.

INACTIVE INGREDIENTS

Peppermint Oil, Eucolyptus Oil, Lavendor Oil, Clove oil, Jasmine Lactone, Stearic Acid, Glyceryl monostearate, Carbomer

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	All Natural Essential Cream for N PAIN G Medica SUPER POWER for DEEP	TTALENT Aaximum Pain Relieving Rub Crea のののののののののののです。 のののののののののののののののののののののののの	作合 DR Active Mer Pepe USI uSI uSI uSI uSI uSI uSI uSI u	an fast relief t JG FACTS ive Ingredien thol 5% ctive ingredien thol 5% ctive ingredien seryl Monostea ES for the te ociated with RNINGS - U: s, mucous r dren. Pack tor using. Do ults, disconti ECTION: it and child that child th	ents: colptus Oil, Lavender Oil, Clove Oil, Jas ate. Carbomer imporary relief of minor aches a simple backache, arthritis and s is only a sdirected. For axterne nembranes, rashes, wounds or t age not child resistant, in case of tely, if prone to allergic reaction not apply on nose and genital area mue use and consult a doctor. ed 12 years of age and older; ap nthy 3 to 4 times daily. Childre y.	E mine Lactone, S nd pains of n trains. I use only. / amages skin accidental i to the product , if raches, ra	PURPOSE xternal Analgesic itearic Acid, nuscles and Joints wold contact with , keep away from ngestion, contact onsault to a doctor idenses itchiness was to affected	Lot #: Exp:	-
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PAIN GOODBYE MEDICATED CREAM menthol 5% cream									
Pro	oduct Information								
Pro	duct T ype	HUMAN OTC DRUG	Ite m Co	de (So	ource)	NDC:1	5667-5049		
Route of Administration TOPICAL									
Active Ingredient/Active Moiety									
Ingredient Name					Basis of Strength		Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)				N	ENTHOL		14 g in 28	30 g	
Inactive Ingredients									
Ingredient Name					Streng	th			
PEPPERMINT OIL (UNII: AV092KU4JH)									
EUCALYPTUS OIL (UNII: 2R040NI662)									
LAVENDER OIL (UNII: ZBP1YXW0H8)									
JASMINE LACTONE (UNII: H8558L43SR)									
STEARIC ACID (UNII: 4ELV7Z65AP)									
GLY	CERYL MONOSTEARATE (UNII:	230 O U9 XXE4)							
CAR	BOMER 1342 (UNII: 809Y72KV36	5)							
CLOVE OIL (UNII: 578389D6D0)									

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15667-5049-4	280 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/26/2011	

Labeler - Austin Biotechnology Inc (656001949)

Registrant - Austin Biotechnology Inc (656001949)

Establishment	Establishment							
Name	Address	ID/FEI	Business Operations					

Indilic	Autress	ID/FEI	Dusiness Operations
Austin Biotechnology Inc		656001949	manufacture(15667-5049)

Revised: 10/2013

Austin Biotechnology Inc