

DR. WALTONS COOL AND HOT ANALGESIC - menthol gel
DR. WALTONS, INCORPORATED

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.

DR. WALTON'S COOL AND HOT ANALGESIC GEL

MENTHOL: 1.0%

TOPICAL ANALGESIC

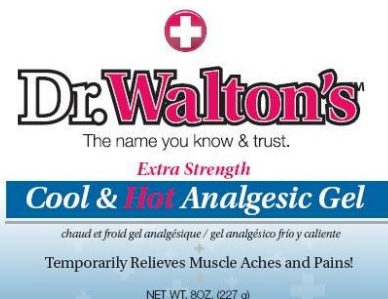
DO NOT APPLY TO CHILDREN UNDER 2 YEARS OF AGE

PROVIDES TEMPORARY RELIEF OF MINOR ACHES AND PAINS IN MUSCLES AND JOINTS ASSOCIATED WITH SIMPLE BACKACHE, STRAINS, ARTHRITIS AND SPORTS INJURIES.

FOR EXTERNAL USE ONLY. NOT FOR INTERNAL USES. AVOID CONTACT WITH EYES OR MUCOUS MEMBRANES. DO NOT APPLY TO OPEN WOUNDS OR DAMAGED SKIN. MAKE SURE SKIN IS CLEAN AND FREE FROM CREAMS, OINTMENTS, SPRAYS OR LINIMENT. DO NOT BANDAGE.

CLEAN SKIN OF ALL OTHER LOTIONS, CREAMS, OINTMENTS, LINIMENT OR SPRAYS. APPLY LIBERALLY TO AFFECTED AREA AND MASSAGE UNTIL ABSORBED INTO SKIN. DO NOT APPLY MORE THAN 3-4 TIMES DAILY. NO PROTECTIVE COVER NEEDED.

WATER, ISOPROPYL ALCOHOL, NONOXYNOL-10, CAMPHOR, CARBOMER, SODIUM HYDROXIDE, METHYLCHLOROISOTHIAZOLINONE AND METHYLISOTHIAZOLINONE, BLUE 1 (CI42090)



Dr. Walton's™ Cool and Hot analgesic gel is a non-greasy pain reliever that starts to work on contact. It penetrates deep to relieve minor aches and pains in your muscles and joints. Provides soothing, long-lasting relief!

Drug Facts

Active Ingredient: Menthol 1.0%
Purpose: Topical Analgesic
Uses: Provides temporary relief of minor aches and pains in muscles and joints associated with simple backache, strains, sprains, arthritis and sports injuries.
Warning: For external use only. Not for internal use. Avoid contact with eyes or mucous membranes. Do not apply to open wounds or damaged skin. Make sure skin is clean before use. Do not use with other creams, ointments, sprays or liniment.
Do not use heating pads or heating devices.
If condition worsens or symptoms persist more than 7 days or if symptoms disappear and occur again within a few days, discontinue use and consult a physician. If you have sensitive skin, consult a physician before use. If skin irritation develops, discontinue use and consult a physician. Stop use immediately if you experience any allergic reaction before use. Do not use, store, pour or spill near heated or open flame. Store in a cool, dry place and keep lid tightly closed.

Directions: Clean skin of all other lotions, creams, ointments, liniment or sprays. Apply liberally to affected area and massage until gel is absorbed into skin. Do not apply more than 3 or 4 times daily. No protective cover needed. Do not apply to children under 2 years of age.
Other ingredients: WATER, ISOPROPYL ALCOHOL, NONOXYNOL-10, CAMPHOR, CARBOMER, SODIUM HYDROXIDE, METHYLCHLOROISOTHIAZOLINONE & METHYLISOTHIAZOLINONE, BLUE 1 (CI 42090).

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DR. WALTONS COOL AND HOT ANALGESIC			
menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76271-003
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.27 g in 227 g

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76271-003-08	227 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/14/2011	

Labeler - DR. WALTONS, INCORPORATED (041377104)

Revised: 6/2011

DR. WALTONS, INCORPORATED