

ULTRA THERAPY PAIN RELIEF- menthol, methyl salicylate and capsaicin lotion
Cal Pharma

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.

METHYL SALICYLATE (28%)

MENTHOL (10%)

CAPSAICIN (0.025%)

TOPICAL ANALGESIC

USE

- TEMPORARILY RELIEVES MILD ACHES AND PAINS OF MUSCLE AND JOINTS

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE ON OPEN WOUNDS, CUTS, DAMAGED OR INFECTED SKIN AS WELL AS IN THE EYES, MOUTH, GENITALS OR OTHER MUCOUS MEMBRANE

STOP USE AND CONSULT YOUR PHYSICIAN IF PAIN IS PERSISTENT OR WORSENS

KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- APPLY ON CLEAN SKIN AND GENTLY RUB OVER AREA WITH PAIN. DO NOT USE MORE THAN 4 TIMES A DAY. WASH HANDS AFTER LOTION IS APPLIED AND RUBBED ONTO SKIN.

INACTIVE INGREDIENTS

Acrylates/C10-30 Alkyl Acrylates Crosspolymer, Butterbur Extract, Cetearyl Alcohol and Polysorbate 60, Glucosamine HCl, Glyceryl Stearate and Peg 100 Stearate, Hydroxypropyl Methylcellulose, Isopropyl Palmitate, Phenoxyethanol, Ethylhexylglycerin, Pine Bark Extract, Prickly Ash Bark Extract, Propylene Glycol, Sichuan Peppercorn Extract, Stearyl Alcohol, Water Deionised, Willowbark Extract, Wintergreen Extract

NDC 55628-1001-02

Ultra Therapy Pain Relief

Topical Pain Relieving Lotion



net wt 120ml / 4 oz

Drug Facts

Active Ingredients	Purpose
Methy Salicylate 2.8%	Topical Analgesic
Menthol 1.0%	
Capsaicin 0.025%	

Use: Temporarily relieves mild aches and pains of muscle and joints

Warnings

For external use only. Do not use on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals or any other mucous membrane. Stop use and consult your physician if pain is persistent or worsens

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away

Directions: Apply on clean skin and gently rub over area with pain. Do not use more than 4 times a day. Wash hands after lotion is applied and rubbed onto skin.

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylates Crosspolymer, Butterbur Extract, Cetearyl Alcohol and Polysorbate 60, Glucosamine HCL, Glyceryl Stearate and PEG100 Stearate, Hydroxypropyl Methylcellulose, Isopropyl Palmitate, Phenoxyethanol Ethylhexyl glycerin, Pine Bark Extract, Prickly Ash Bark Extract, Propylene Glycol, Sichuan Peppercorn Extract, Stearyl Alcohol, Water Deionised, Willowbark Extract, Wintergreen Extract

Distributed By: CAL PHARMA
MADE IN THE USA

ULTRA THERAPY PAIN RELIEF

menthol, methyl salicylate, capsaicin lotion

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55628-1001
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (MENTHOL)	MENTHOL	10 g in 100 mL
METHYL SALICYLATE (SALICYLIC ACID)	METHYL SALICYLATE	28 g in 100 mL
CAPSAICIN (CAPSAICIN)	CAPSAICIN	.025 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)	
PETASITES HYBRIDUS LEAF	
CETOSTEARYL ALCOHOL	
POLYSORBATE 60	

GLUCOSAMINE HYDROCHLORIDE	
GLYCERYL MONOSTEARATE	
PEG-100 STEARATE	
HYPROMELLOSES	
ISOPROPYL PALMITATE	
PHENOXYETHANOL	
ETHYLHEXYLGLYCERIN	
MARITIME PINE	
ZANTHOXYLUM AMERICANUM BARK	
PROPYLENE GLYCOL	
ZANTHOXYLUM BUNGEANUM WHOLE	
STEARYL ALCOHOL	
WATER	
WILLOW BARK	
GAULTHERIA PROCUMBENS LEAF	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55628-1001-2	120 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/29/2012	

Labeler - Cal Pharma (078721283)