

PAINMD MAX- capsaicin, histamine dihydrochloride cream
OMG Medical Group, LLC

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.

PainMD Max

Active Ingredients

Capsaicin 0.0375% USP

Histamine Dihydrochloride 0.035% USP

Warnings

For external use only

do not ingest

use only as directed

do not bandage tightly or use external heat or a heating pad

avoid contact with eyes, mucous membranes, vagina, penis, scrotum and anus. If eye contact occurs, rinse thoroughly with water

do not use on open wounds or damaged skin

do not use if you are allergic to ingredients in this product

stop and ask doctor if: condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, irritation develops, redness is present

if swallowed, get medical help or contact a poison control center right away

If pregnant or breast-feeding ask a health professional before use

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Caprylic/Capric Triglyceride, Cetyl Alcohol, Cetyl Myristoleate, Cucumis Sativus (Cucumber) Extract, Ethylhexylglycerin, Glycerin, Glycyrrhiza Glabra (Licorice) Extract, Ilex Paragauyensis (Yerba Mate) Extract, Isopropyl Myristate, Methylsulfonylmethane (MSM), PEG-8, Phenoxyethanol, Sodium Lauryl Sulfate, Triethanolamine

Directions

Adults and children over 12 years: apply a thin layer to the pain site and massage gently until thoroughly absorbed into the skin, repeat as necessary but not more than 4 times daily.

Children 12 years or younger: ask a doctor

Wash hands immediately after use.

Other information

store at controlled room temperature between 15 degrees C and 30 degrees C (59F-86F) with cap

closed tight

do not use if tamper resistant seal on jar is torn, broken or missing

Keep out of reach of children

Purpose

Topical Analgesic

Pain relief



PAINMD MAX

capsaicin, histamine dihydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55992-404
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	3.75 mg in 1 mg
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	3.5 mg in 1 mg

Inactive Ingredients

Ingredient Name	Strength
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(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)
water (UNII: 059QF0KO0R)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
BOSWELLIA SACRA WHOLE (UNII: 8O600AZL0W)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CETYL ALCOHOL (UNII: 936JST6JCN)
CETYL MYRISTOLEATE (UNII: 87P8K33Q5X)
CUCUMIS SATIVUS WHOLE (UNII: 50560UL2YV)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)
ILEX PARAGUARIENSIS WHOLE (UNII: QJB02841ZY)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
PEG-8 CAPRYLIC/CAPRIC GLYCERIDES (UNII: 00BT03FSO2)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55992-404-11	3.75 mg in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/22/2014	

Labeler - OMG Medical Group, LLC (038837214)

Establishment

Name	Address	ID/FEI	Business Operations
OMG Medical Group, LLC		038837214	repack(55992-404)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture(55992-404)