QR PAIN- analgesic cream
MARYHELENE ENTERPRISES 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.

QR PAIN CREAM 5g

DRUG FACTS

Active Ingredient

Mannitol 30%

Menthol 1.25%

Purpose

Topical Analgesic

Uses

for the temporary relief of pain.

Warnings

For external use only.

When using this product

- do not bandage tightly
- avoid contact with the eyes
- do not apply to wounds or damaged skin
- do not use with heating pads or other heating devices
- as with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product
- do not use in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if

Condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and older, apply to affected area no more than 3-4 times a day. **Children under 12 years of age**: do not use, contact a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Inactive Ingredients

Lecithin, Ethylhexylglycerin, Ceteareth 20, Glyceryl stearate, Octyldodecanol, Phenoxyethanol, Propylene glycol, Isopropyl Palmitate, Caprylic/Capric triglyceride, Dimethicone, Polyethylene glycol 100 stearate, Water, Cetearyl alcohol.

Questions or Comments?

1-833-772-7326 (1 833 QR CREAM) or visit www.qrcream.com

QR PAIN CREAM 5g (NDC 73180-005-00)

QR PAIN

analgesic cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73180-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MANNITOL (UNII: 3OWL53L36A) (MANNITOL - UNII:3OWL53L36A)	MANNITOL	30 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73180-005-01	1 in 1 BOX	12/01/2019	
1	NDC:73180-005-00	5 g in 1 TUBE; 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	12/01/2019	

Labeler - MARYHELENE ENTERPRISES INC (203935056)

Registrant - MARYHELENE ENTERPRISES INC (203935056)

Revised: 1/2023 MARYHELENE ENTERPRISES INC