

GLUCOSAMINE CREAM EXTRA STRENGTH- histamine dihydrochloride cream **IDEAZ, 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.

Glucosamine Cream EXTRA STRENGTH

▯Drug Facts

A▯ctive Ingredient

Histamine Dihydrochloride 0.05%

▯Purpose

Topical Analgesic

▯Uses For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains

▯Warnings For external use only

▯When using this product

- Avoid contact with eyes
- Do not bandage tightly

▯Do not use

- On wounds or damaged skin or if you are allergic to ingredients in this product.

▯Discontinue use and consult a physician if: Condition worsens or if symptoms persists 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

▯Directions

For use by adults and children over 12 years:

Apply to affected area not more than 3 to 4 times daily.

▯Inactive ingredients Deionized water, cetearyl alcohol, emu oil, glycerine, ceteareth-

20, glucosamine sulfate, dimethyl sulfone, caprylic capric triglyceride, phenoxyethanol, cetyl alcohol, methyl paraben, tocopherol acetate, butylene glycol, propylene glycol, chamomilla recutita flower extract, rosmarinus officinalis leaf extract, boswellia serrata extract, propyl paraben

Pain Relief On Contact

Dual Action Moisturizing Cream

Odorless, Greaseless, Stainless.

Made in USA

For re-orders call 800-280-5590

www.drnewtons.com

Distributed by

Dr. Newton's Naturals

26 Thomas Drive

Westbrook, ME 04092

Packaging

DR. NEWTON'S™ NATURALS

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GLUCOSAMINE CREAM EXTRA STRENGTH

histamine dihydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78983-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.05 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EMU OIL (UNII: 344821WD61)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL ALCOHOL (UNII: 936JT6JCN)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CHAMOMILE (UNII: FGL3685T2X)	
ROSEMARY (UNII: IJ67X351P9)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78983-101-85	85 g in 1 TUBE; Type 0: Not a Combination Product	09/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/08/2022	

Labeler - IDEAZ, LLC (873184431)