TACT COOL JELLY- diphenhydramine hydrochloride, levomenthol gel
Sato Pharmaceutical Co., Ltd.

Tact Cool Jelly

Active ingredients

Diphenhydramine Hydrochloride 2.0%
l-Menthol 1.0%

Uses

temporarily relieves pain and itching associated with
■insect bites ■minor skin irritations ■minor cuts
■scrapes ■rashes due to poison ivy ■sunburn ■minor burns

Warnings
For external use only

When using this product

■avoid contact with the eyes

Stop use and ask a doctor if

■condition worsens ■symptoms persist for more than 7 days.

■symptoms 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 2 years and over: Apply to affected area not more than 3 to 4 times daily. ■Children under 2 years: Ask a doctor.

I **nactive ingredients** alcohol, BHT, carboxyvinyl polymer, hydroxypropyl cellulose, monoethanolamine, nonoxynol 9, polysorbate 80, propylene glycol, purified water.

Diphenhydramine Hydrochloride	External analgesic
l-Menthol	External analgesic

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TACT COOL JELLY

diphenhydramine hydrochloride, levomenthol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49873-704
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 g
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	

NONOXYNOL-9 (UNII: 48Q180SH9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-704-01	1 in 1 CARTON	10/02/1997	
1		20 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 Drug	M017	10/02/1997	

Labeler - Sato Pharmaceutical Co., Ltd. (690575642)

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-704) , label(49873-704) , pack(49873-704)

Revised: 12/2023 Sato Pharmaceutical Co., Ltd.