TACT- diphenhydramine hydrochloride, menthol cream
Sato Pharmaceutical Inc., Ltd.

Tact Cream

Active ingredients
Diphenhydramine hydrochloride 2.0%
Menthol 1.0%

Purpose
Diphenhydramine Hydrochloride External analgesic
l-Menthol External analgesic

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

Warnings
For rectal 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.

Inactive ingredients butylparaben, carboxyvinyl polymer, cetyl alcohol, diethanolamine, edetate disodium, light mineral oil, PEG-40 stearate, propylene glycol, propylparaben, purified water, sorbitan monostearate, white petrolatum.

tactcreamcart.jpg

TACT

diphenhydramine hydrochloride, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49873-705
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
DIETHANOLAMINE (UNII: AZE05TDV2V)	
EDETATE SODIUM (UNII: MP1J8420LU)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-705-01	1 in 1 CARTON	09/09/1997	
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	09/09/1997	

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

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Inc., Ltd.		715699133	manufacture(49873-705) , label(49873-705) , pack(49873-705)

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