# ALLERGY RELIEF DYE FREE- diphenhydramine hcl capsule, liquid filled TOPCO ASSOCIATES 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.

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# **TopCare health Dye-Free Allergy Relief**

#### Active ingredient (in each capsule)

Diphenhydramine HCl 25 mg

#### Purpose

Antihistamine

#### Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, runny nose, itchy, watery eyes, itching of the nose or throat
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, runny nose

#### Warnings

#### Do not use

- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

# Ask a doctor before use if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

# Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

# When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

# If pregnant or breast-feeding,

ask a health professional before use.

# Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

#### Directions

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours
- swallow whole; do not crush, chew or dissolve
- adults and children 12 years of age and over take 1 to 2 softgels
- children 6 to under 12 years of age take 1 softgel
- children under 6 years of age do not use

#### Other information

- store between 20-25°C (68 to 77°F). Avoid high humidityandexcessive heat.
- Protect from light, heat, humidity

#### Inactive ingredients

gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol-sorbitan solution, titanium dioxide

#### **Questions or comments?**

Call 1-888-333-9792

# PRINCIPAL DISPLAY PANEL

Compare to Benadryl® Dye-Free LIQUI-GELS® active ingredient\*

Allergy Relief

Diphenhydramine HCl 25 mg/Antihistamine

Dye-Free

temporarily Relieves:

Sneezing Runny Nose Itchy, Watery Eyes Itchy Nose or Throat Softgels

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl®, or Catalent Pharma Solutions, Inc., owner of the registered trademark LIQUI-GELS®.



<b>Product Informati</b>	on						
Product Type	]	HUMAN OTC DRUG Item Code (Source) NI		NDC:36800	NDC:36800-933		
Route of Administrati	on	ORAL					
Active Ingredient/	Active Moie	ty					
	Ingree	dient Name		Basis of St	trength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - DIPHENHYDRAMINE UNII:8GTS82S83M) DIPHENHYDRAMINE HYDROCHLORIDE						25 mg	
Inactive Ingredien	St	Strength					
GELATIN (UNII: 2G86Q	N327L)						
GLYCERIN (UNII: PDC6							
POLYETHYLENE GLY		B697894SGQ)					
POVIDONE (UNII: FZ98							
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
WATER (UNII: 059QF0K							
SORBITOL (UNII: 506T60A25R) TITANIUM DIOXIDE (UNII: 15FIX9V2JP)							
TTANIOM DIO AIDE (O	NII. 13F1A9 V2JP	)					
	ristics						
Product Character			0		no score		
Product Character Color	white		Score				
	white CAPSULE		Score Size		14mm		

Packaging									
#	Item Code	Package Description	Marketing Start Date	Marketing End Date					
1 N	DC:36800-933-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2020						
Ma	arketing Info	rmation							
	arketing Info	rmation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					

Labeler - TOPCO ASSOCIATES LLC (006935977)

# Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment									
Name	Address	ID/FEI	Business Operations						
MEDGEL PVT LTD		677385498	manufacture(36800-933)						

Revised: 2/2020

TOPCO ASSOCIATES LLC