

SOHMED ALLERGY- diphenhydramine hydrochloride tablet
SOHM 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.

SohMed™ Allergy

Drug Facts

Active ingredients (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

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

Warnings

Do not use with any other product containing diphenhydramine, even one used on skin.

Ask a doctor before use if you have

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

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.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take every 4 to 6 hours
- do not take more than 6 times in 24 hours

adults and children 12 years and over	1 to 2 caplets
children 6 to under 12 years	1 caplet
children under 6 years	consult a doctor

Other information

- Store between 20°-25°C (68°-77°F).
Avoid high humidity. Protect from light
- See end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, D&C Red #27, hydroxypropylmethyl cellulose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide, May contain polysorbate.

Question or comments?

1 (856) 2863646

Distributed by : **Sohm, Inc.**
6920 Knott Ave., Suit A-C,
Buena Park, CA 90621

PRINCIPAL DISPLAY PANEL - 24 Caplet Bottle Carton

NDC XXXXXXXXXXXX

SohMed™

***Compare to the active ingredients in Benadryl® Allergy Ultratab®**

Antihistamine

Allergy

Diphenhydramine HCl 25 mg

24 Caplets

- ***Runny Nose • Itchy, Watery Eyes***
- ***Sneezing • Itchy throat***



SOHMED ALLERGY

diphenhydramine hydrochloride tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50405-004

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Product Characteristics

Color	RED	Score	2 pieces
Shape	OVAL	Size	11mm
Flavor		Imprint Code	CRX
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50405-004-24	1 in 1 CARTON		
1		24 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/25/2013	

Labeler - SOHM Inc. (009303848)