# CLEMASTINE FUMARATE - clemastine fumarate tablet Physicians Total Care, Inc.

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#### **Drug Facts**

#### **Active ingredient**

Clemastine fumarate 1.34 mg (equivalent to 1 mg clemastine)

# **Purpose**

Antihistamine

#### Keep out of reach of children.

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

#### Uses

Temporarily relieves these symptoms of the common cold, hay fever, or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

#### Warnings

### Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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

- you may get drowsy
- 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.

#### **Directions**

adults and chituren 12 years and older:	24 hours	
children under 12 years:	ask a doctor	

#### Other Information

- Safety sealed: do not use if the imprinted bottle seal is open or torn.
- Store at 20°-25°C (68°-77°F).

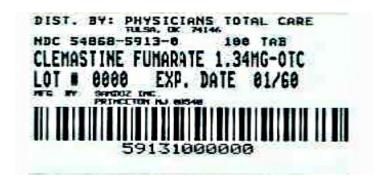
## **Inactive Ingredients**

Hydroxypropyl methylcellulose, lactose (monohydrate), magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and starch (corn).

#### Questions or comments?

1-800-525-8747

#### PRINCIPAL DISPLAY PANEL



NDC 54868-5913-0

Clemastine

**Fumarate** 

Tablets, USP

1.34 mg

100 Tablets

Antihistamine

12 Hour Relief

Relief of: Sneezing Runny Nose

Itchy, Watery Eyes

#### **CLEMASTINE FUMARATE**

clemastine fumarate tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5913(NDC:0781-1358)	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety				
ı	Ingredient Name	Basis of Strength	Strength		
ı	CLEMASTINE FUMARATE (UNII: 19259EGQ3D) (CLEMASTINE - UNII:95QN29S1ID)	CLEMASTINE FUMARATE	1.34 mg		

Inactive Ingredients				
Ingredient Name	Strength			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
STARCH, CORN (UNII: O8232NY3SJ)				
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0 VUT3PMY82)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	CAPSULE (capsule shaped)	Size	4mm
Flavor		Imprint Code	GG;159
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:54868-5913-0	100 in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA073458	06/27/2008		

# **Labeler -** Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 5/2012 Physicians Total Care, Inc.