

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

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 children 12 years and older	1 tablet every 12 hours; not more than 2 tablets in
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adults and children 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		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE 2910 (3 MPAS) (UNII: 0VUT3PMY82)	
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			

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