

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE-
cetirizine hcl, pseudoephedrine hcl tablet, extended release
A-S Medication Solutions

Perrigo Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Drug Facts

Active ingredients (in each extended release tablet)

Cetirizine HCl 5 mg

Pseudoephedrine HCl 120 mg

Purpose

Antihistamine

Nasal Decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- nasal congestion
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease

- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are

taking tranquilizers or sedatives.

When using this product

- do not use more than directed
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: 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.

Directions

- do not break or chew tablet; swallow tablet whole

adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.
adults 65 years and over	ask a doctor
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc, yellow iron oxide

Questions or comments?

1-800-719-9260

HOW SUPPLIED

Product: 50090-1098

NDC: 50090-1098-1 1 TABLET, EXTENDED RELEASE in a BLISTER PACK / 24 in a CARTON

NDC: 50090-1098-0 30 TABLET, EXTENDED RELEASE in a BOTTLE

Cetirizine HCl, Pseudoephedrine HCl



CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

cetirizine hcl, pseudoephedrine hcl tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-1098(NDC:45802-721)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE -	CETIRIZINE HYDROCHLORIDE	5 mg

UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg		
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg		
Inactive Ingredients				
Ingredient Name		Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
TALC (UNII: 7SEV7J4R1U)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
Product Characteristics				
Color	WHITE (one side white one side light yellow)	Score	no score	
Shape	ROUND	Size	12mm	
Flavor		Imprint Code	5029;5;120	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-1098-1	24 in 1 CARTON	11/28/2014	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50090-1098-0	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077170	04/10/2008		

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-1098)