CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE- cetirizine hcl, pseudoephedrine hcl tablet, extended release
Perrigo New York Inc

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

Principal Display Panel

Compare to Zyrtec-D® active ingredients

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride

Extended Release Tablets

5 mg/120 mg

Antihistamine / Nasal Decongestant

12 Hour Relief of:

Sneezing

Itchy, Watery Eyes

Runny Nose

Itchy Throat or Nose

Sinus Pressure

Nasal Congestion

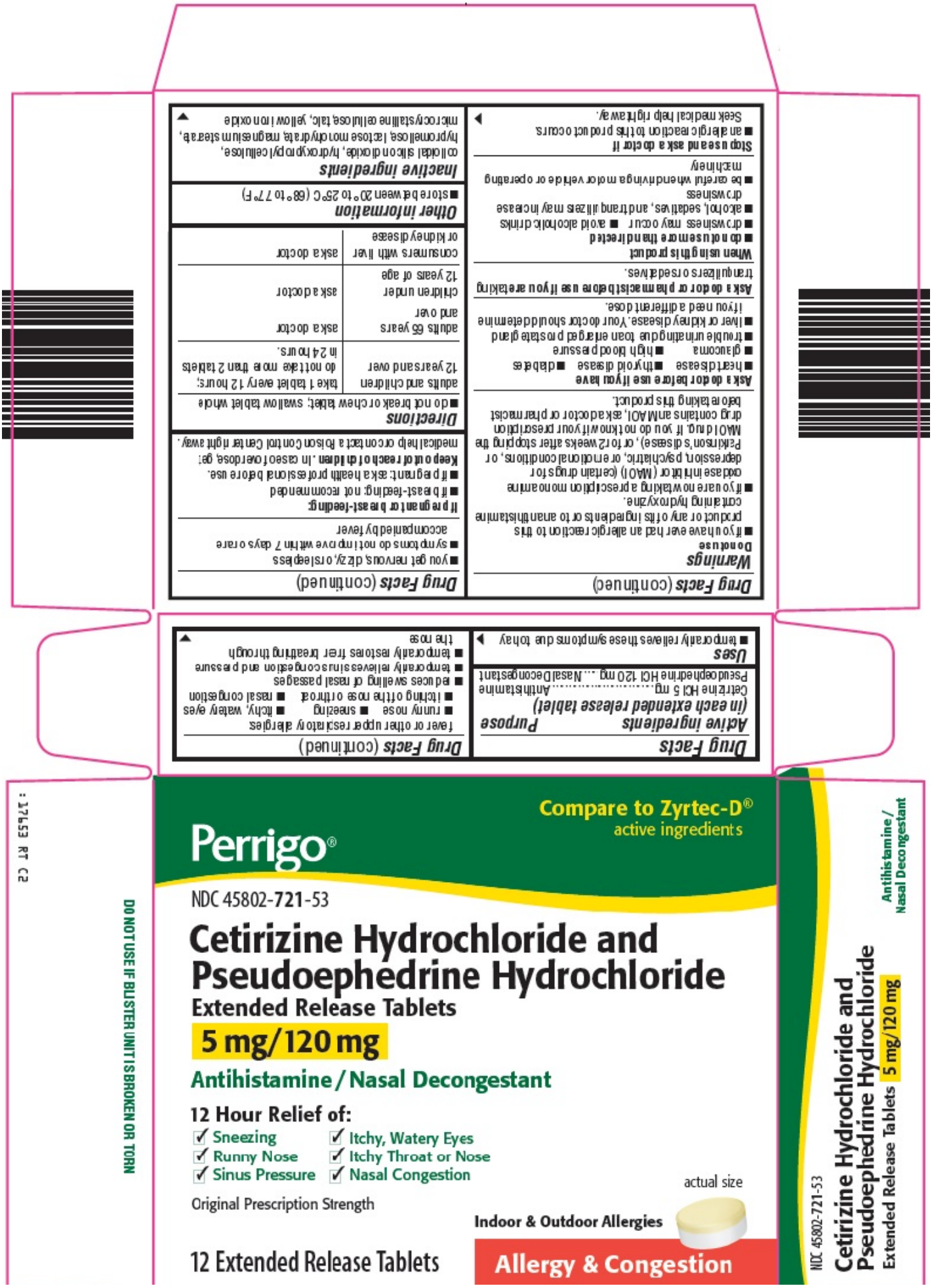
actual size

Original Prescription Strength

Indoor & Outdoor Allergies

12 Extended Release Tablets

Allergy & Congestion



Perrigo®

Compare to Zyrtec-D®
active ingredients

NDC 45802-721-53

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride

Extended Release Tablets

5 mg/120 mg

Antihistamine / Nasal Decongestant

12 Hour Relief of:

- ✓ Sneezing
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- ✓ Sinus Pressure
- ✓ Itchy, Watery Eyes
- ✓ Itchy Throat or Nose
- ✓ Nasal Congestion

Original Prescription Strength

actual size

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12 Extended Release Tablets

Allergy & Congestion

Antihistamine / Nasal Decongestant

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride
Extended Release Tablets 5 mg/120 mg

NDC 45802-721-53

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

LT453 RT C2

Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

cetirizine hcl, pseudoephedrine hcl tablet, extended release

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - 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 (TYPE H) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (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:45802-721-62	24 in 1 CARTON	04/10/2008	

1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:45802-721-53	12 in 1 CARTON	05/16/2014	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077170	04/10/2008	

Labeler - Perrigo New York Inc (078846912)

Revised: 9/2016 Perrigo New York Inc