CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Publix Super Markets Inc

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Cetirizine HCl, USP 10 mg

PURPOSE

Antihistamine

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

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.

Ask a doctor before use if you have

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

- 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.

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 (1-800-222-1222).

DIRECTIONS

adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**
- store between 68° to 77° F (20° to 25° C)

INACTIVE INGREDIENTS

Corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Carton

NDC 56062-939-60

INDOOR & OUTDOOR ALLERGIES
ORIGINAL PRESCRIPTION STRENGTH
24-HOUR

allergyrelief

CETIRIZINE HYDROCHLORIDE TABLETS USP, 10 mg

ANTIHISTAMINE

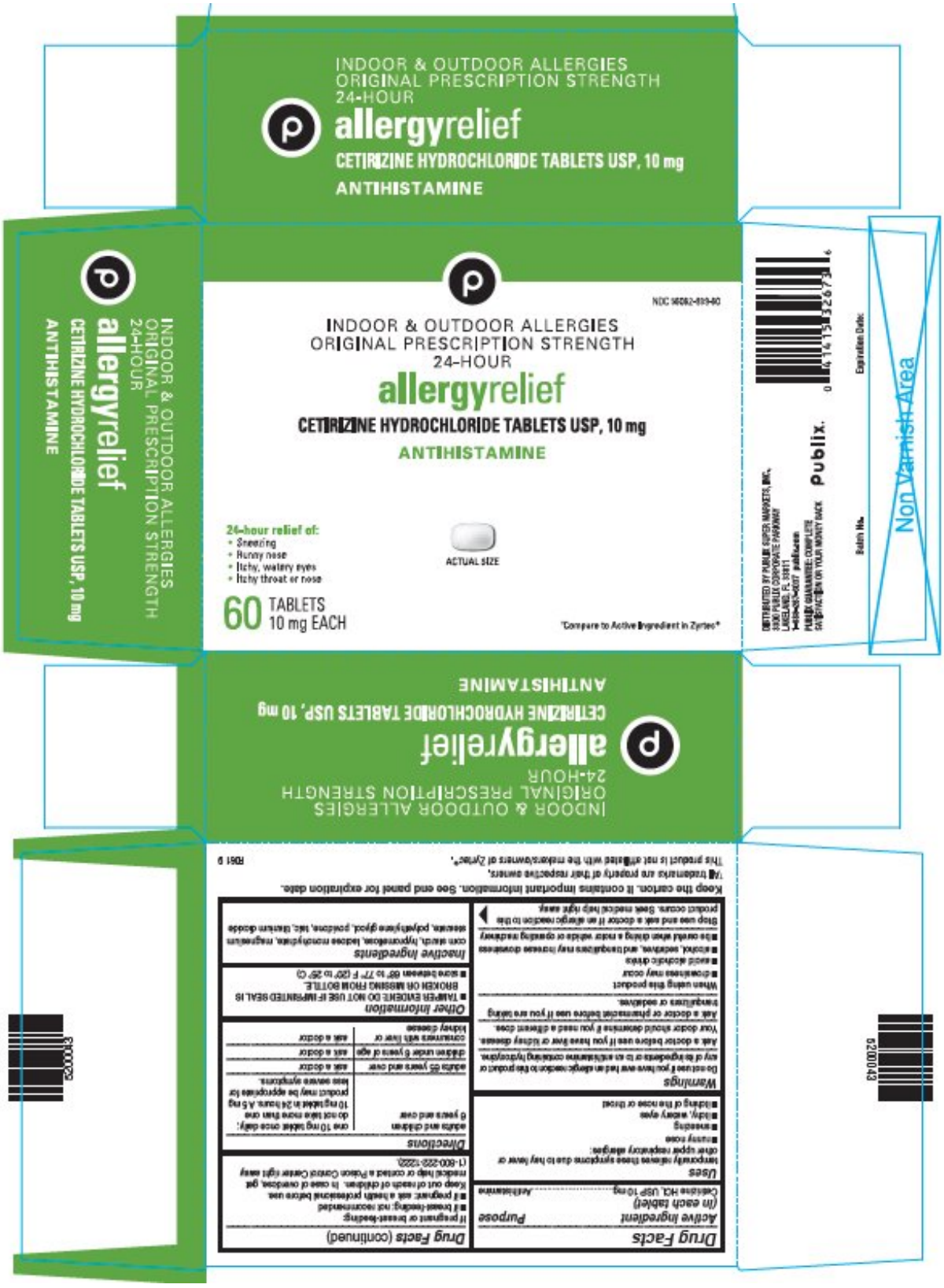
24-hour relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

ACTUAL SIZE

60
TABLETS
10 mg EACH

†Compare to Active Ingredient in Zyrtec®



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56062-939

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	RECTANGLE (Rounded-Off)	**Size**	9mm
Flavor		**Imprint Code**	R152
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-939-54	14 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/27/2007	
2	NDC:56062-939-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	
3	NDC:56062-939-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077498	12/27/2007	

Labeler - Publix Super Markets Inc (006922009)

Registrant - Sun Pharmaceutical Industries Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations

Ohm Laboratories Inc.		184769029	manufacture(56062-939)