CETIRIZINE HYDROCHLORIDE TABLETS,10 MG- cetirizine hydrochloride tablet
Northwind Pharmaceuticals, LLC

Cetirizine hydrochloride tablets USP 10 mg

DRUG FACTS

Active ingredient (in each tablet)
Cetirizine HCl 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	one 10 mg tablet once daily; do not take more than one 10 mg tablet

children 6 years and over	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

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

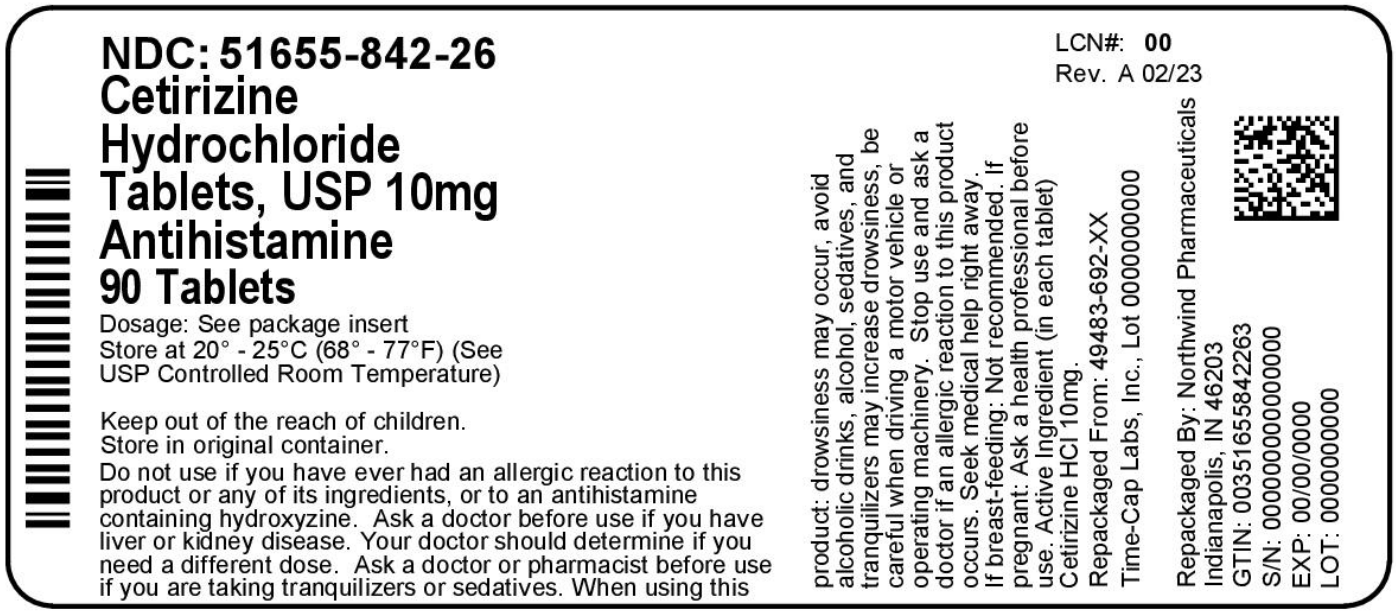
Inactive ingredients corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, titanium dioxide

Questions or comments?

Call **1-877-290-4008**

Principal Display Panel

NDC 51655-842-26



CETIRIZINE HYDROCHLORIDE TABLETS,10 MG

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51655-842(NDC:49483-692)
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	white (White to off white)	**Score**	no score
Shape	RECTANGLE (Rounded-off rectangular shaped)	**Size**	9mm
Flavor		**Imprint Code**	J;220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-842-26	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/07/2023	
2	NDC:51655-842-84	14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/10/2023	
3	NDC:51655-842-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2023	
4	NDC:51655-842-52	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078933	02/07/2023	

Labeler - Northwind Pharmaceuticals, LLC (036986393)

Registrant - Northwind Pharmaceuticals, LLC (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals, LLC		036986393	repack(51655-842)

Revised: 4/2023