CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Denton Pharma, Inc. DBA Northwind Pharmaceuticals

Cetirizine Hydrochloride Tablets USP, 10 mg, Allergy

ACTIVE INGREDIENTS

Active Ingredients (in each tablet) **Purpose**

Cetirizine HCl USP 10 mg.....Antihistimine

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 DOCTOR

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

ASK DOCTOR/PHARMACIST

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

WHEN USING THIS PRODUCT

- drowsines may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinary.

STOP USE

Stop use and ask a doctor if an allergic reaction tothis 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 Poison Control Center right away.

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

store at 20° to 25°C (68° to 77°F)

[See USP Controlled Room Temperature]

INACTIVE INGREDIENTS

Hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide.

QUESTIONS?

Call 1-866-562-4597

Manufactured by:

Unique Pharmaceutical Labs.

(A Div. of J. B. Chemicals & Pharmaceuticals Ltd.),
Mumbai 400 030, India

Distributed by:

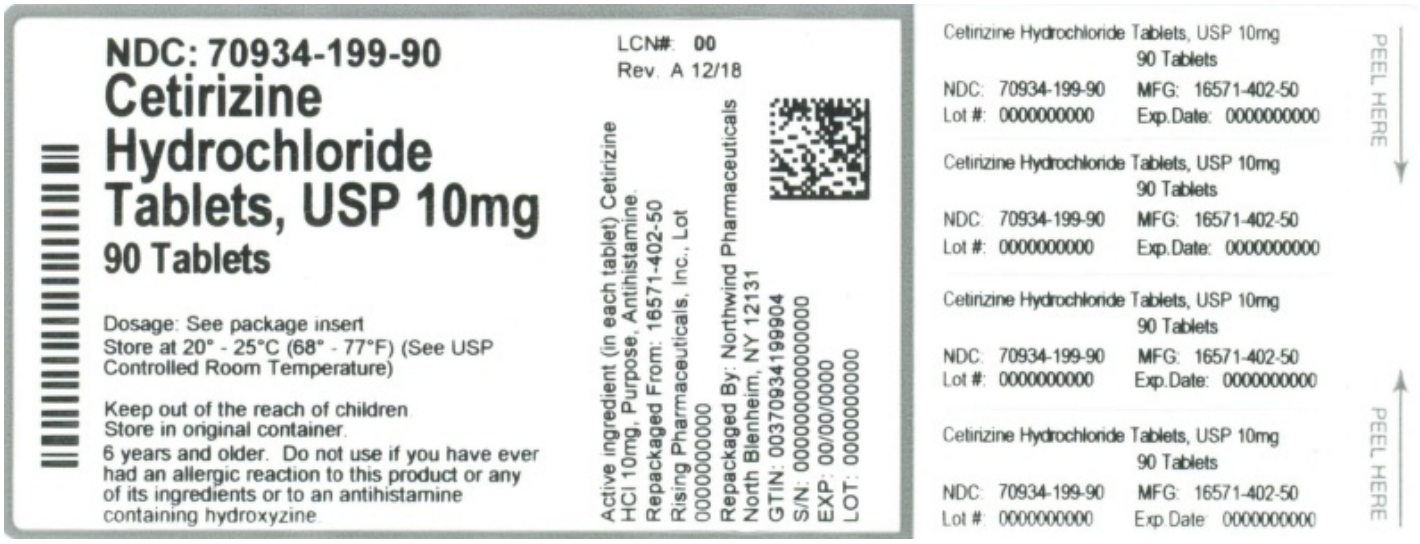
Rising Pharmaceuticals, Inc.
Saddle Brook, NJ 07663

M. L. G/1430 May 2018

120005

Principal Display Panel

NDC: 70934-199-90



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70934-199(NDC:16571-402)
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**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (White)	**Score**	no score
Shape	BULLET (Barrel Shaped)	**Size**	8mm
Flavor		**Imprint Code**	CTN;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70934-199-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/04/2018	09/30/2024
2	NDC:70934-199-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/29/2019	03/31/2024
3	NDC:70934-199-97	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/29/2019	10/31/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	12/04/2018	09/30/2024

Labeler - Denton Pharma, Inc. DBA Northwind Pharmaceuticals (080355546)

Registrant - Denton Pharma, Inc. DBA Northwind Pharmaceuticals (080355546)

Establishment

Name	Address	ID/FEI	Business Operations
Denton Pharma, Inc. DBA Northwind Pharmaceuticals		080355546	repack(70934-199)