CETIRIZINE HYDROCHLORIDE (HIVES RELIEF) - cetirizine hydrochloride tablet
Aurohealth LLC

Drug Facts

Active ingredient (in each tablet)

For 5 mg:

Cetirizine hydrochloride USP 5 mg

For 10 mg:

Cetirizine hydrochloride USP 10 mg

Purpose

Antihistamine

Uses

relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Warnings

Severe Allergy Warning: Get emergency help **immediately** if you have hives along with any of the following symptoms:

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue
- swelling in or around mouth
- trouble speaking
- drooling
- wheezing or problems breathing

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

- to **prevent** hives from any known cause such as:
  - foods
  - insect stings
  - medicines
  - latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

- 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.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

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.
- symptoms do not improve after 3 days of treatment.
- the hives have lasted more than 6 weeks.

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

For 5 mg:

adults and children 6 years and over	1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours
adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours.
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

For 10 mg:

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

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions?

call **1-855-274-4122**

Keep the carton. It contains important information.

Manufactured for:
AUROHEALTH LLC
2572 Brunswick Pike
Lawrenceville, NJ 08648

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 072, India

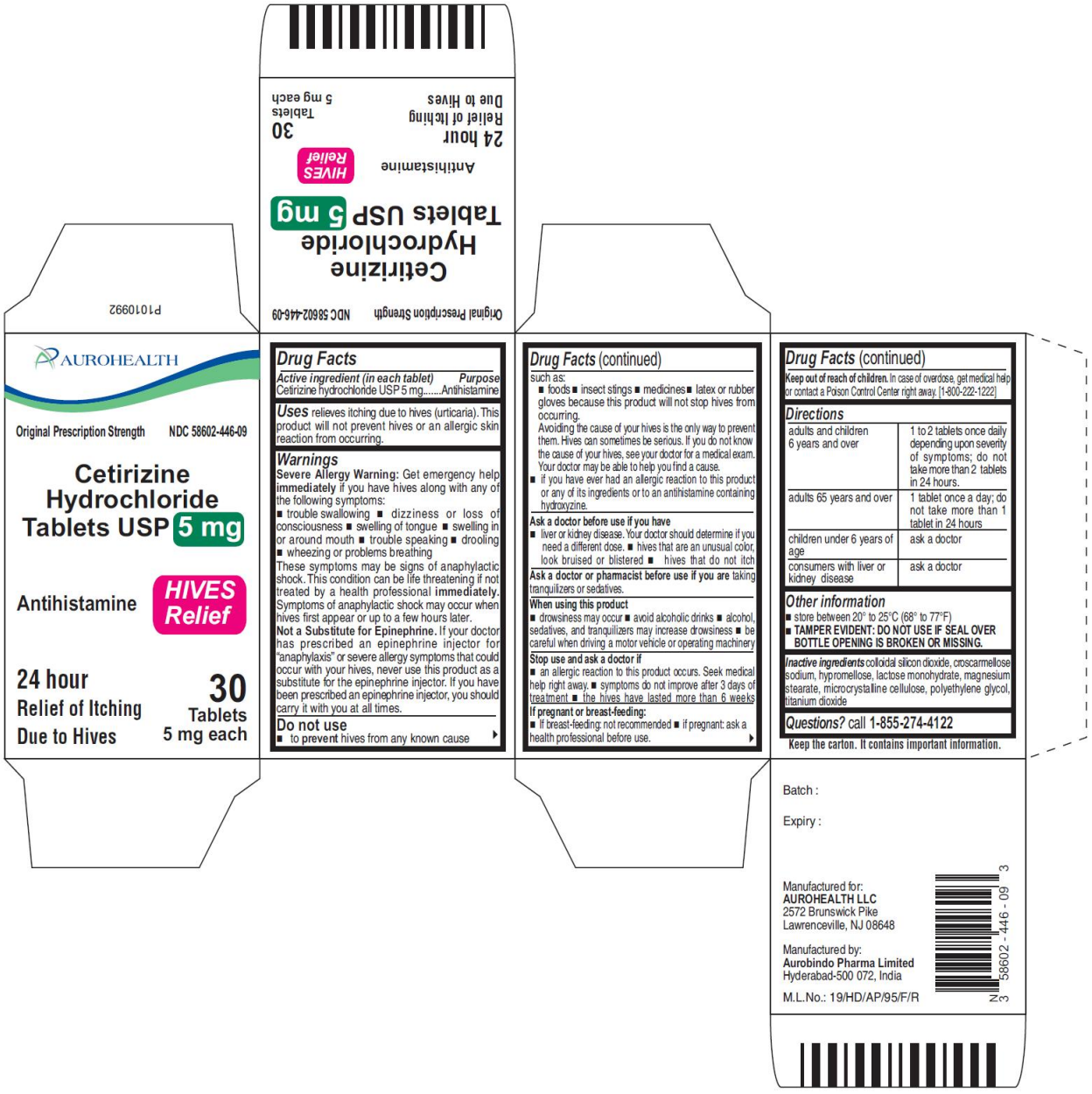
M.L.No.: 19/HD/AP/95/F/R

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg (30's Tablet Container Carton Label)

AUROHEALTH
Original Prescription Strength **NDC 58602-446-09**
Cetirizine
Hydrochloride
Tablets USP 5 mg
Antihistamine HIVES Relief

24 hour
Relief of Itching
Due to Hives

30
Tablets
5 mg each



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 5 mg (10 x 10 Blister Carton

Label)

AUROHEALTH
NDC 58602-446-21
Original Prescription Strength
Cetirizine
Hydrochloride
Tablets USP
5 mg
Antihistamine
HIVES Relief

24 hour
Relief of Itching Due to Hives

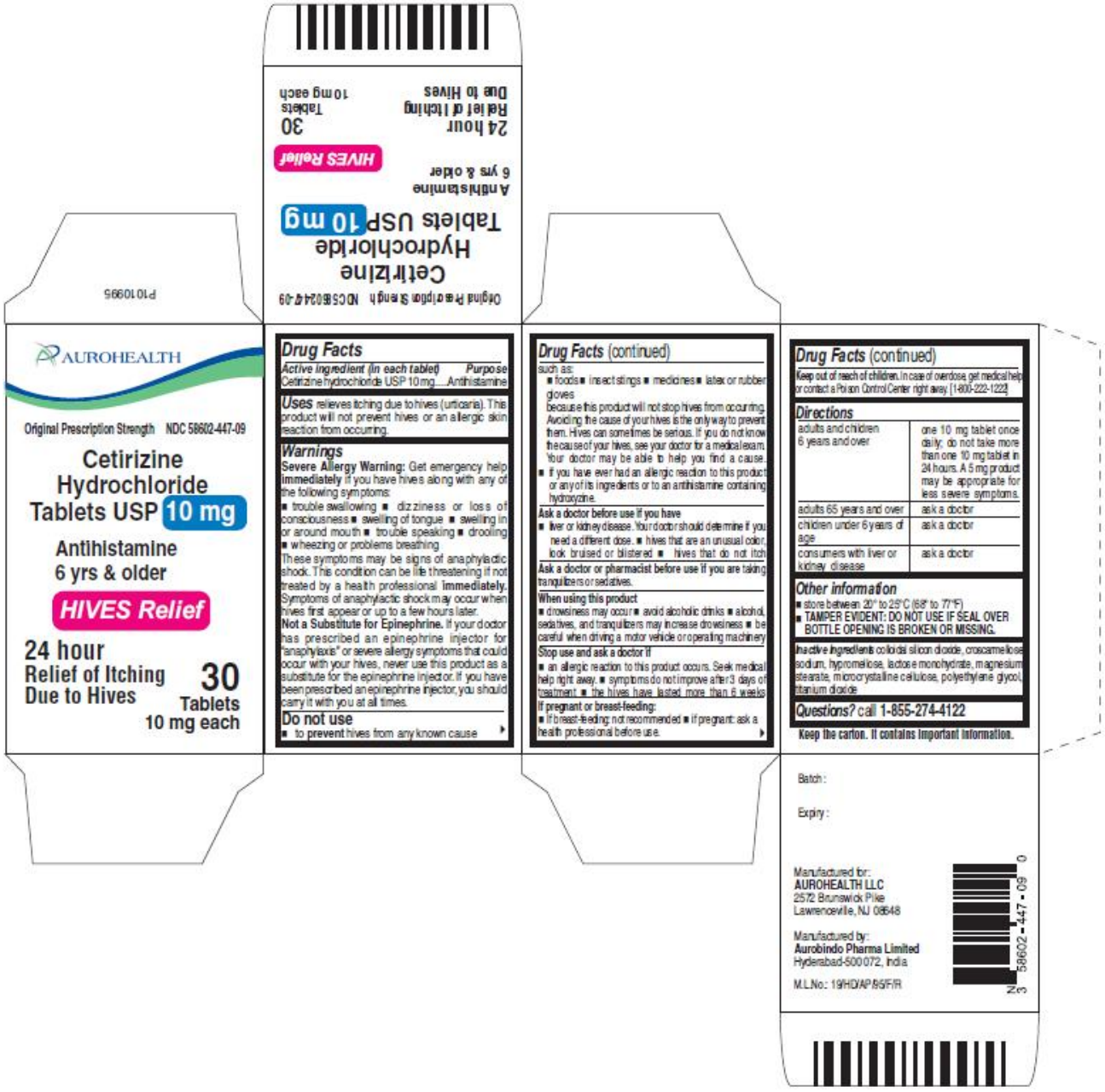
100 (10 x 10) Unit-dose Tablets

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (30's Tablet Container Carton Label)

AUROHEALTH
Original Prescription Strength
NDC 58602-447-09
Cetirizine
Hydrochloride
Tablets USP 10 mg

Antihistamine
6 yrs & older
HIVES Relief
24 hour
Relief of itching
Due to Hives

30
Tablets
10 mg each



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (10 x 10 Blister Carton Label)

AUROHEALTH
NDC 58602-447-21
Original Prescription Strength
Cetirizine
Hydrochloride
Tablets USP
10 mg
Antihistamine
6 yrs & older
HIVES Relief

24 hour
Relief of Itching Due to Hives
100 (10 x 10) Unit-dose Tablets

CETIRIZINE HYDROCHLORIDE (HIVES RELIEF)

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-446
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

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White to Off-white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	X;35
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58602-446-09	1 in 1 CARTON	08/05/2015	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-446-17	1 in 1 CARTON	08/05/2015	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-446-47	75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	08/05/2015	
4	NDC:58602-446-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
5	NDC:58602-446-21	10 in 1 CARTON	08/05/2015	
5		10 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	ANDA090760	08/05/2015	

CETIRIZINE HYDROCHLORIDE (HIVES RELIEF)

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-447
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White to Off-white)	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	X;36
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-447-09	1 in 1 CARTON	08/05/2015	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-447-17	1 in 1 CARTON	08/05/2015	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-447-47	75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	08/05/2015	
4	NDC:58602-447-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
5	NDC:58602-447-21	10 in 1 CARTON	08/05/2015	
5		10 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	ANDA090760	08/05/2015	

CETIRIZINE HYDROCHLORIDE (HIVES RELIEF)

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-813
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White to Off-white)	**Score**	2 pieces
Shape	RECTANGLE (off-rectangular)	**Size**	9mm
Flavor		**Imprint Code**	X;2;0
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58602-813-09	1 in 1 CARTON	08/05/2015	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-813-17	1 in 1 CARTON	08/05/2015	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-813-99	75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	08/05/2015	
4	NDC:58602-813-23	1 in 1 CARTON	08/05/2015	
4		120 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-813-39	1 in 1 CARTON	08/05/2015	
5		365 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-813-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
7	NDC:58602-813-04	10 in 1 CARTON; Type 0: Not a Combination Product	08/05/2015	

8	NDC:58602-813-83	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/05/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090760	08/05/2015	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-446, 58602-447, 58602-813) , MANUFACTURE(58602-446, 58602-447, 58602-813)

Revised: 11/2022 Aurohealth LLC