LEADER ALL DAY ALLERGY - cetirizine tablet
Cardinal Health

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.** ***(for bottle cartons/labels only)***
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.** ***(for blister cartons only)***
- store between 20° to 25° C (68° to 77° F)

INACTIVE INGREDIENTS

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

QUESTIONS?

call **1-800-406-7984**

KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION. SEE END PANEL FOR EXPIRATION DATE.

PRINCIPAL DISPLAY PANEL

LEADER®

NDC 37205-0825-74

Indoor & Outdoor Allergies

Compare to Zyrtec® active ingredient†

ORIGINAL PRESCRIPTION STRENGTH

AllDayAllergy

Cetirizine HCl Tablets, 10 mg/Antihistamine

24 Hour Relief of:

- **Sneezing**
- **Runny Nose**
- **Itchy, Watery Eyes**
- **Itchy Throat or Nose**

14TABLETS 10 mg EACH

†This product is not manufactured or distributed by McNeil-PPC, Inc.,distributor ofZyrtec®. Zyrtec®is a registered trademark of UCB Pharma, S.A.

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Zyrtec® is a registered trademark of UCB Pharma, S.A.

R0512

14 TABLETS 10 mg EACH

SATISFACTION GUARANTEED

Cetirizine HCl Tablets, 10 mg/Antihistamine

24 Hour Relief of:
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• Itchy, Watery Eyes • Itchy Throat or Nose

Allergy

All Day

ORIGINAL PRESCRIPTION STRENGTH

Indoor & Outdoor Allergies

LEADER®

Compare to Zyrtec® active ingredient*

NDC 37205-820-74

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 4595047
www.myleader.com 1-800-200-6313

0 96295 12306 7

Non Varnish Area

Batch No.

Expiration Date:

5096144

5096144

Drug Facts

Active ingredient (in each tablet) — **Purpose**

Cetirizine HCl, USP 10 mg ..... Antihistamine

Uses

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Drug Facts (continued)

- runny nose
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Inactive ingredients

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Keep the carton. It contains important information.
See end panel for expiration date.

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Drug Facts

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0612

5096449

5096449

Non Varnish Area

Batch No.

Expiration Date:

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 4601845
www.myleader.com 1-800-200-6313

0 96295 12327 2

120 TABLETS 10 mg EACH

SATISFACTION GUARANTEED

24 Hour Relief of:
• Sneezing
• Itchy, Watery Eyes
• Runny Nose
• Itchy Throat or Nose

Cetirizine HCl Tablets, 10 mg/Antihistamine

Allergy

All Day

ORIGINAL PRESCRIPTION STRENGTH

Indoor & Outdoor Allergies

LEADER®

Compare to Zyrtec® active Ingredient†

NDC 37205-820-76

LEADER®

ORIGINAL PRESCRIPTION STRENGTH
All Day
Allergy

Cetirizine HCl Tablets, 10 mg/Antihistamine

Indoor & Outdoor Allergies

LEADER®

ORIGINAL PRESCRIPTION STRENGTH
All Day
Allergy

Cetirizine HCl Tablets, 10 mg/Antihistamine

Indoor & Outdoor Allergies

LEADER ALL DAY ALLERGY

cetirizine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-820
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	white	**Score**	no score
Shape	RECTANGLE (rounded-off)	**Size**	9mm
Flavor		**Imprint Code**	RI52
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:37205-820-74	14 in 1 BLISTER PACK		
2	NDC:37205-820-65	30 in 1 BOTTLE		
3	NDC:37205-820-70	45 in 1 BOTTLE		
4	NDC:37205-820-75	90 in 1 BOTTLE		
5	NDC:37205-820-76	120 in 1 BOTTLE		

Marketing Information

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

Labeler - Cardinal Health (097537435)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(37205-820)

Revised: 3/2012 Cardinal Health