ALL DAY ALLERGY RELIEF- cetirizine hcl tablet P & L Development, LLC

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:
 - o 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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- 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 (1-800-222-1222) right away.

Directions

adults and children 6 Take 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.

years and over

adults 65 years and

over

ask a doctor

children under 6 years of age

ask a doctor

consumers with

liver or kidney

ask a doctor

disease

Other Information

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

• contains no ingredient made from a gluten-containing grain(wheat, barley or rye)

Inactive ingredients

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

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Compare to the active ingredient in **Zyrtec**®*

all day allergy relief

cetirizine HCl 10 mg

antihistamine

treats indoor & outdoor allergies

original prescription strength

24 hour relief of:

- sneezing
- itchy, watery eyes
- runnv nose
- itchy throat or nose

tablets

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Zyrtec®.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by:

PL Developments

200 Hicks Street Westbury, NY 11590

Package Labeling

help or contact a Poison Control Center (1-800-222-1222) right keep out of reach of children, in case of overdose, get medical

- if pregnant: ask a health professional before use
 - if breast-feeding: not recommended
 - If pregnant or breast-feeding:

occurs. Seek medical help right away. Stop use and ask a doctor if an allergic reaction to this product

- pe cerețul when driving a motor vehicle or operating machinery
- sicopol, sedatives, and tranquilizers may increase drowsiness
 - quowajueas way occur
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broduct or any of its ingredients or to an antihistamine containing Do not use if you have ever had an allergic reaction to this Warnings

- m riching of the nose or throat
- m runny nose m sneezing m itchy, watery eyes

nbber respiratory allergies:

Temporanly relieves these symptoms due to hay tever or other

Antihistamine Cetifizine HCl 10 mg.

(in each tablet) Active ingredient

Purpose

Drug Facts

McNeil Consumer Healthcare, distributor of Zyrtec®. Li his product is not manufactured or distributed by

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST Questions or comments?

glycol, tranium dioxide wagnesium stearate, microcrystalline cellulose, polyethylene croscarmellose sodium, hypromellose, lactose monohydrate, Inactive ingredients colloidal silicon dioxide,

grain (wheat, barley or rye)

- contains no ingredient made from a gluten-containing
 - store between 20° to 25°C (68° to 77°F)

Uther information

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

Drug Facts (continued)

all day allergy relief

cetirizine HCl tablets 10 mg antihistamine



Compare to the active ingredient in Zyrtec®*

NDC 59726-806-14

all day allergy relief

cetirizine HCl 10 ma antihistamine



DENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER ORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

treats indoor & outdoor allergies

ariainal propariation atranath

onginal prescription strength

24-hour relief of:

- sneezingitchy, watery eyesrunny noseitchy throat or nose

14 tablets







PLD-A539A FC005342



READYinCASE All Day Allergy Relief

ALL DAY ALLERGY RELIEF

cetirizine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-806
Route of Administration	ORAL		

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	CETIRIZINE HYDRO CHLO RIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg	

Inactive Ingredients		
Ingredient Name	Strength	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		

Product Characteristics				
Color	WHITE	Score	2 pieces	
Shape	OVAL	Size	9 mm	
Flavor		Imprint Code	G;4	

Contains

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59726-806-05	5 in 1 CARTON	06/30/2018			
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:59726-806-14	14 in 1 CARTON	06/30/2018			
2		1 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	ANDA209274	06/30/2018		

$\pmb{Labeler} ~\textbf{-} ~ \textbf{P} ~\&~ \textbf{L} ~ \textbf{Development}, \textbf{LLC} ~ (800014821)$

Revised: 12/2019 P & L Development, LLC