CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, coated
Safrel Pharmaceuticals, LLC

Cetrizine Hydrochloride Tablets

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Drug Facts

Active Ingredient

Cetirizine HCl 10 mg

PURPOSE

Antihistamine

USE(S)

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

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

liver or kidney disease. Your doctor should determine if you need a different dose.

ASK A DOCTOR OR PHARMACIST BEFORE USE IF

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 DOCTOR IF

an allergic reaction to this product occurs. Seek medical help right away.

PREGNANCY/BREASTFEEDING

- 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

STORAGE

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

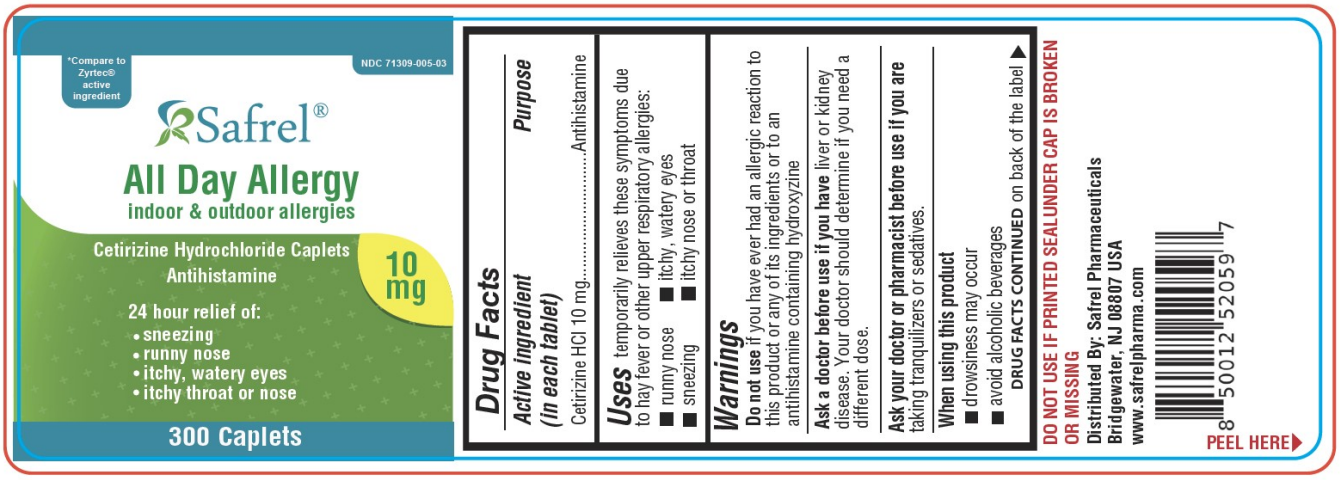
Other information

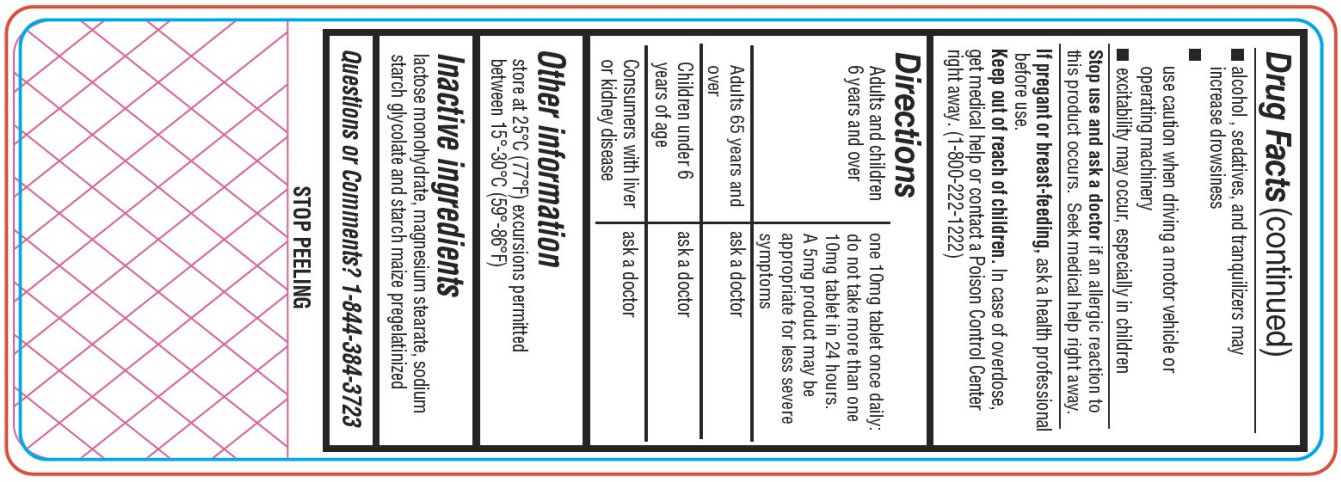
Contains no ingredient made from a gluten-containing grain (wheat, barley or rye).

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL





CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71309-005
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**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	white (white to off white)	**Score**	2 pieces
Shape	RECTANGLE (rounded off rectangualr)	**Size**	9mm
Flavor		**Imprint Code**	G;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-005-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209274	05/28/2018	

Labeler - Safrel Pharmaceuticals, LLC (080566287)

Revised: 10/2020 Safrel Pharmaceuticals, LLC