APTRIZINE 24-HOUR ALL DAY ALLERGY - cetirizine hydrochloride tablet
A P J Laboratories Limited

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active ingredient
CETIRIZINE HYDROCHLORIDE

Purpose
Antihistamine

Keep out of reach of children
Keep out of reach of children.In case of overdose, get medical help or contact a Poison Control Center right away.

Indications and Usage
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.

Warning
If you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Dosage and Administration
Adults and children 6years andover 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 65years and over: ask a doctor.

Children under 4-6 years of age: ask a doctor

Children under 4 years of age: ask a doctor

Consumers with liver or kidney disease: ask a doctor

Inactive Ingredient
LACTOSE MONOHYDRATE

Inactive Ingredient

STARCH, CORN

Inactive Ingredient
GELATIN

Inactive Ingredient
METHYLPARABEN

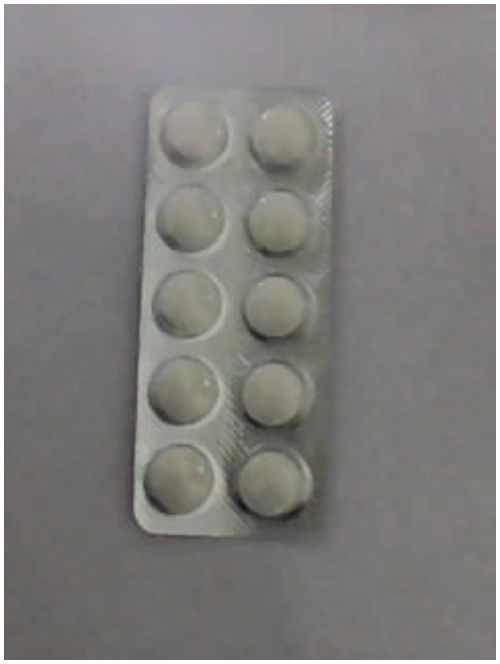
Inactive Ingredient
TITANIUM DIOXIDE

Inactive Ingredient
MAGNESIUM STEARATE

Inactive Ingredient
TALC

Inactive Ingredient
SODIUM STARCH GLYCOLATE TYPE A POTATO

DISPLAY PANEL



APTRIZINE 24-HOUR ALL DAY ALLERGY

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46084-012
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)	21.66 mg
STARCH, CORN (UNII: O8232NY3SJ)	85.32 mg
GELATIN (UNII: 2G86QN327L)	2.4 mg
METHYLPARABEN (UNII: A2I8C7HI9T)	.2 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	.1 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	1.3 mg
TALC (UNII: 7SEV7J4R1U)	3.9 mg
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	3.9 mg

Product Characteristics			
Color	white (white)	**Score**	no score
Shape	ROUND (no score)	**Size**	7mm
Flavor		**Imprint Code**	10mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-012-15	120 in 1 BLISTER PACK		
2	NDC:46084-012-14	60 in 1 BLISTER PACK		
3	NDC:46084-012-13	45 in 1 BLISTER PACK		
4	NDC:46084-012-12	30 in 1 BLISTER PACK		
5	NDC:46084-012-11	15 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA019835	02/21/2013	

Labeler - A P J Laboratories Limited (677378339)

Registrant - A P J Laboratories Limited (677378339)

Establishment

Name	Address	ID/FEI	Business Operations
A P J Laboratories Limited		677378339	manufacture(46084-012)

Revised: 2/2013 A P J Laboratories Limited