LORATADINE- loratadine tablet Blenheim Pharmacal, Inc.

Loratadine Tablet 10 mg

Drug Facts

Active ingredient (in each tablet)

Loratadine 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

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

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

If pregnant or breast-feeding, 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.

Directions

adults and children 6 years and over	1 tablet daily; not 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	

Other information

• safety sealed: do not use if induction seal, with "Lift N Peel" tab, under cap is broken or missing

- store between 2° and 30°C (36° and 86°F)
- protect from exceesive moisture

Inactive ingredients

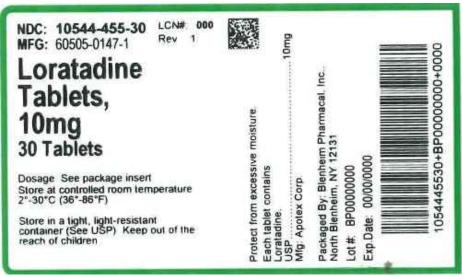
colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose

Manufactured by: Manufactured for: Apotex Inc. Apotex Corp.
Toronto, Ontario Weston, Florida
Canada M9L 1T9 33326

Revised: March 2005

Principal Display Panel Loratadine Tablets, USP 10mg 30 Tablets

NDC 10544-455-30





LORATADINE

loratadine tablet

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10544-455(NDC:60505-0147)		
Route of Administration	ORAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg	

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	8 mm
Flavor		Imprint Code	LOR;10;APO
Contains			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:10544-455-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076471	02/09/2014	

Labeler - Blenheim Pharmacal, Inc. (171434587)

Registrant - Blenheim Pharmacal, Inc. (171434587)

Establishment			
Name	Address	ID/FEI	Business Operations
Blenheim Pharmacal, Inc.		171434587	repack(10544-455)

Revised: 2/2015 Blenheim Pharmacal, Inc.