LORATADINE- loratadine tablet
Contract Pharmacy Services-PA

Drug Facts 453

Active Ingredient (in each tablet)

Loratadine, USP 10 mg

Purpose

Antihistamine

Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- 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 the imprinted bottle seal is open or torn (for bottle only).
- Safety sealed: do not use if open or torn (for blister package only).
- Store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature).

Inactive Ingredients

Lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

Questions or comments?

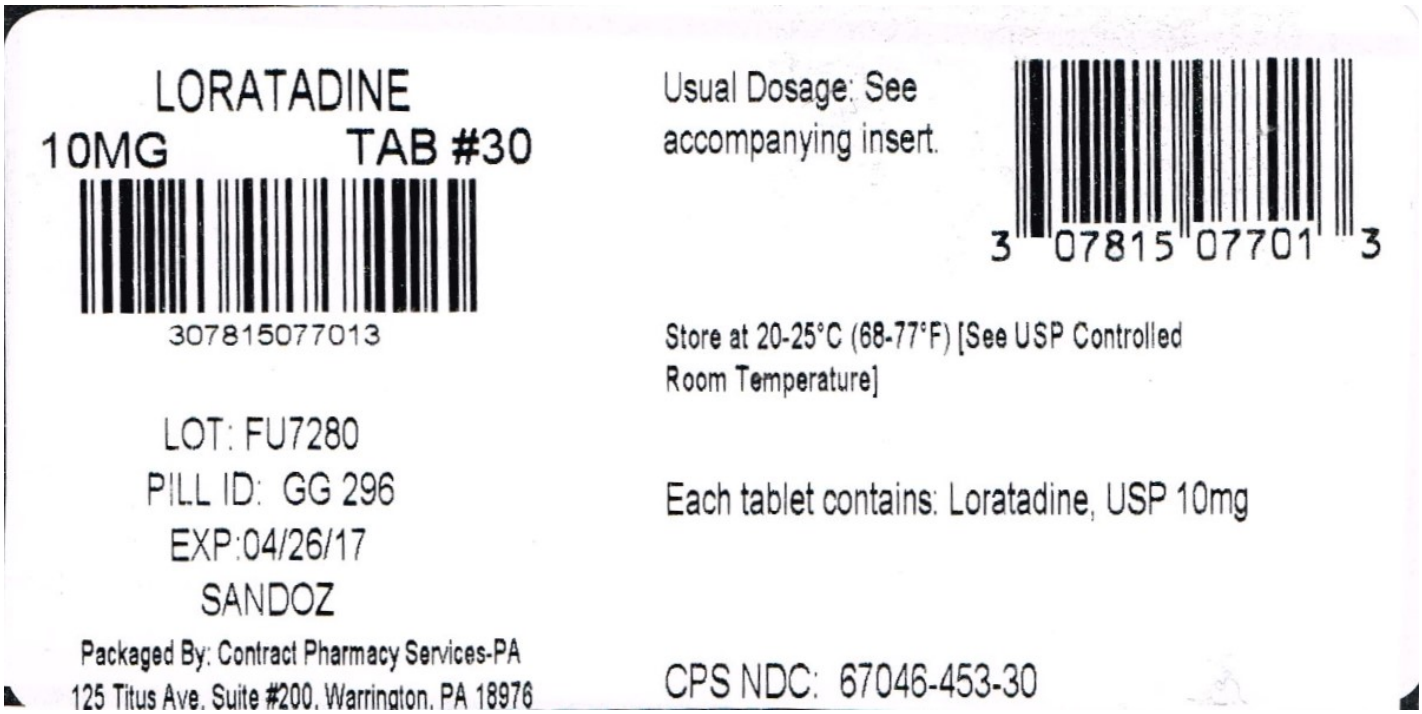
1-800-525-8747

10-2015M

Sandoz Inc.

Princeton, NJ 08540

10 mg Label



NDC 67046-453-30 Non-Drowsy*

Loratadine

Tablets, USP

10 mg

Antihistamine

Indoor & Outdoor Allergies

30 Tablets

SANDOZ

24 Hour

Relief of:

Sneezing

Runny Nose

Itchy, Watery

Eyes

Itchy Throat

or Nose

* When taken as directed.

See Drug Facts Panel.

LORATADINE

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67046-453(NDC:0781-5077)
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**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	white (white to off white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	GG296
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67046-453-07	7 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
2	NDC:67046-453-14	14 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
3	NDC:67046-453-15	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
4	NDC:67046-453-21	21 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	

5	NDC:67046-453-28	28 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
6	NDC:67046-453-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	
7	NDC:67046-453-60	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075209	09/19/2017	

Labeler - Contract Pharmacy Services-PA (945429777)

Establishment

Name	Address	ID/FEI	Business Operations
Coupler Enterprises		945429777	repack(67046-453)

Revised: 9/2017 Contract Pharmacy Services-PA