LORATADINE- loratadine tablet Spirit Pharmaceuticals LLC

Loratadine Tablets, 10 mg

Active ingredient

Loratadine 10 mg

Purpose

Antihistamine

Uses

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

- runny nose
- sneezing
- itchy, water 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 usung 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 diseaseask a doctor

Other information

- Tamper-evident: do not use if foil under cap is missing, open or broken
- store between 20^o to 25^oC (68^o to 77^oF)

Inactive ingredients

Lactose monohydrate, magnesium stearate, povidone, starch maize pregelatinized

Questions or comments?

1-888-333-9792

DISPLAY PANEL

NON-DROWSY* Original Prescription Strength Loratadine Tablets, 10 mg / Antihistamine Indoor & Outdoor Allergies 24 Hour Relief of: • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose 365 Tablets *When taken as directed See Drug Facts Panel



	C								
	2								
loratadine tablet									
Due de et la ferm									
Product Information									
Product Type		HUMAN OTC DRUG	ltem Code	Code (Source)		NDC:68210-4126			
Route of Adminis	stration	ORAL							
Active Ingredi	ent/Active	Moiety							
	Ingredient Name Basis of St				renath	Strength			
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) LORATADINE						10 mg			
			- /,						
Inactive Ingredients									
Ingredient Name						Strength			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)									
STARCH, CORN (UN	III: 08232NY35))							
POVIDONE (UNII: FZ	2989GH94E)								
MAGNESIUM STEA	RATE (UNII: 700	097M6I30)							
Product Chara									
Color	white (White to off white)			Score		no score			
Shape	ROUND			Size		6mm			
Flavor			Impr	int Code	P;1	0			
Contains									
Packaging									
# Item Code	Pa	ckage Description	Ма	rketing Start Date	Marketing End Date				
				Date		Date			

4126-1	Product	U4/U//ZUZ1						
Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
ANDA	ANDA214684	04/07/2021						

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 11/2022

Spirit Pharmaceuticals LLC