

LORATADINE - loratadine capsule, liquid filled
Strides Pharma Inc

Loratadine Capsules, 10 mg

Liquid-Filled Capsules

Drug Facts

Active ingredient (in each capsule)

Loratadine 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

OTC - DO NOT USE

Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

OTC - ASK DOCTOR

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

OTC - WHEN USING

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

OTC - STOP USE

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

medical help right away.

OTC - PREGNANCY OR BREAST FEEDING

If pregnant or breast-feeding, ask a health professional before use.

OTC - 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.

Directions

adults and children 6 years and over	1 capsule daily; not more than 1 capsule 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 individual blister unit imprinted with Loratadine capsule is open or torn
- store between 20° to 25°C (68° to 77°F)
- protect from freezing

Inactive ingredients

FD & C Blue 1, Gelatin, Glycerin, Glyceryl Monocaprylocaprate, Isopropyl alcohol, Medium chain triglyceride, Polysorbate 80, Povidone K-30, Purified Water, Soya Lecithin, Sorbitol Solution,

Printing ink white-edible oil-Dewaxed Bleached Shellac Resins, Propylene Glycol, Sodium Lauryl Sulphate, Titanium Dioxide

Questions or comments?

Strides Pharma Inc. at 1-877-244-9825 or go to www.strides.com

Manufactured by:

Strides Pharma Science Limited

Bengaluru - 562106, India.

Distributed by:

Strides Pharma Inc.

East Brunswick, NJ 08816

Revised: 01/2020

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NO VARNISH ZONE

NDC 59556-882-01

Strides Pharma Inc.

Non-Drowsy*

Loratadine Capsules, 10 mg

Antihistamine Indoor & Outdoor Allergies

* When taken as directed.
See Drug Facts Panel.

24
hour

- Relief of:
- Sneezing
 - Runny Nose
 - Itchy, Watery Eyes
 - Itchy Throat or Nose

10 LIQUID-FILLED CAPSULES

Loratadine Capsules, 10 mg
Antihistamine
10 CAPSULES FOR 10 DAYS OF RELIEF



Loratadine Capsules, 10 mg
Antihistamine

10 CAPSULES FOR 10 DAYS OF RELIEF

88096901

Drug Facts

Active ingredient (in each capsule) Purpose
Loratadine 10 mg.....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.

Drug Facts (Continued)

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• safety sealed: do not use if the individual blister unit imprinted with Loratadine Capsule 10 mg is open or torn
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FD & C Blue 1, Gelatin, Glycerin, Glyceryl Monocaprylocaprate, Isopropyl alcohol, Medium chain triglyceride, Polysorbate 80, Povidone K-30, Purified Water, Soya Lecithin, Sorbitol Solution, Printing ink white-edible oil- Dewaxed Bleached Shellac Resins, Propylene Glycol, Sodium Lauryl Sulphate, Titanium Dioxide

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LOT } To be
EXP } over printed

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Code No.: KR/DRUGS/XXX/XX/XXX/XX

Revised: 01/2020



GRAIN DIRECTION

LORATADINE

loratadine capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59556-882
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)	LORATADINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C00X)	
GLYCERYL CAPRYLATE/CAPRATE (UNII: G7515SW10N)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
NONCRYSTALLIZING SORBITOL SOLUTION (UNII: 9E0S3UM200)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-882-81	3 in 1 CARTON	06/01/2021	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59556-882-01	1 in 1 CARTON	06/01/2021	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211926	06/01/2021	

Labeler - Strides Pharma Inc (078868278)

Registrant - Strides Pharma Science Limited (650738743)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(59556-882) , MANUFACTURE(59556-882) , PACK(59556-882)

Revised: 3/2022

Strides Pharma Inc