

LORATADINE ALLERGY RELIEF- loratadine tablet
Marlex Pharmaceuticals, Inc.

Loratadine Allergy Relief

Drug Facts

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 (1-800-222-1222).

Directions

adults and children 6 years and over	1 tablet daily; not more than 1 tablet in 24 hours
children under 6 years of	ask a doctor

age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other Information

- store between 20° to 25° C (68° to 77° F)
- protect from excessive moisture
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

Inactive ingredients

corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

Manufactured for/ Distributed by:

Marlex Pharmaceuticals, Inc.

New Castle, DE 19720

Rev. 10/22 SP

PRINCIPAL DISPLAY PANEL

Loratadine 10mg Tablets

NDC 10135-0763-30

30 Tablets

NDC 10135-0763-30

MARLEX

PHARMACEUTICALS, INC.

Loratadine Tablets

10 mg

30 TABLETS

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** **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 doctor if an allergic reaction to this product occurs. Seek medical help right away.
If pregnant or breastfeeding, ask a health professional before use.
Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

store between 20 and 25° C (68 and 77° F) **protect from excessive moisture**
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

Inactive ingredients

corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

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Rev. 10/22 SP

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6

Loratadine 10mg Tablets

NDC 10135-0763-90

90 Tablets

NDC 10135-0763-90

MARLEX
PHARMACEUTICALS, INC.

Loratadine
Tablets

10 mg

90 TABLETS

Drug Facts

Active ingredient (in each tablet) 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.
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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

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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

Inactive ingredients

corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

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Rev. 10/22 SP

Loratadine 10mg Tablets

NDC 10135-0763-03

300 Tablets

NDC 10135-0763-03

MARLEX
PHARMACEUTICALS, INC.

Loratadine
Tablets

10 mg

300 TABLETS

Drug Facts

Active ingredient (in each tablet) 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 doctor if an allergic reaction to this product occurs. Seek medical help right away.
If pregnant or breastfeeding, ask a health professional before use.
Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

Inactive ingredients

corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

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Rev. 10/22 SP

LORATADINE ALLERGY RELIEF

loratadine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-763
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
STARCH, CORN (UNII: O8232NY3SJ)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I3O)			

Product Characteristics

Color	white (White to Off White)	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	RX526
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-763-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
2	NDC:10135-763-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
3	NDC:10135-763-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076134	10/01/2022	

Labeler - Marlex Pharmaceuticals, Inc. (782540215)

Revised: 11/2023

Marlex Pharmaceuticals, Inc.