

LORATADINE SOFTGELS- loratadine capsule, liquid filled
Wal-Mart Stores Inc

WALMART 686T

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

DO NOT USE IF YOU HAVE EVER HAD AN ALLERGIC REACTION TO THIS PRODUCT OR ANY OF ITS INGREDIENTS.

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 BREASTFEEDING, ASK A HEALTH PROFESSIONAL BEFORE USE.

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.
- side effects occur.

If pregnant or breast-feeding, ask a health care 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 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

STORE BETWEEN 20-25 DEGREES CELSIUS (67-77 DEGREES FAHRENHEIT)

PROTECT FROM FREEZING

Inactive ingredients

FD&C BLUE #1, GELATIN, MONO AND DIGLYCERIDE OF CAPRYLIC/CAPRIC ACID, PHARMACEUTICAL INK, POLYSORBATE 80, POVIDONE, PURIFIED WATER, SORBITOL SORBITAN SOLUTION.

NDC 49035-686-30

LORATADINE SOFTGELS

loratadine capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-686
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
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
GLYCERYL CAPRYLOCAPRATE (UNII: U72Q2I8C85)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONES (UNII: FZ989GH94E)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	3mm
Flavor		Imprint Code	21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-686-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206214	06/04/2018	

Labeler - Wal-Mart Stores Inc (051957769)

Registrant - TIME CAP LABS INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49035-686)

Revised: 5/2018

Wal-Mart Stores Inc