## LORATADINE- loratadine capsule, liquid filled CVS HEALTH CORP

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**CVS 686T** 

**LORATADINE 10MG** 

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 BREAST FEEDING, ASK A HEALTH PROFESSIONAL BEFORE USE.

## **ANTIHISTAMINE**

TEMPORARILY RELIEVES THESE SYMPTOMS DUE TO HAY FEVER OR OTHR UPPER RESPIRATORY ALLERGIES:

**RUNNY NOSE** 

ITCHY, WATERY EYES

**SNEEZING** 

ITCHING OF THE NOSE OR THROAT

IN CASE OF OVERDOSE, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

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.

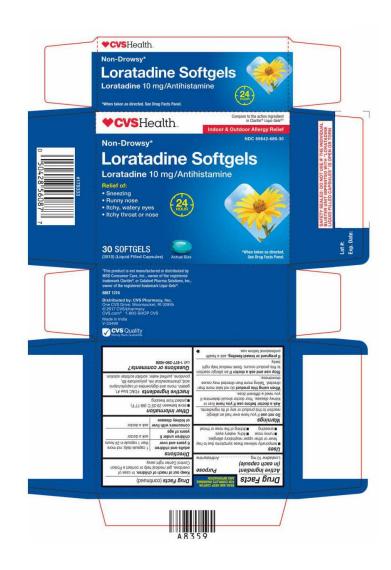
CONSUMERS WITH LIVER OR KIDNEY DISEASE: ASK A DOCTOR.

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

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

## **Loratadine 10 mg Capsules**

Loratadine 10 mg Capsules are supplied in 10, 30 and 60 count blisters



loratadine capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-686
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength
l	LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg

Inactive Ingredients				
Ingredient Name	Strength			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
POLYSORBATE 80 (UNII: 6OZP39 ZG8 H)				
PO VIDO NE (UNII: FZ989 GH94E)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)				

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

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69842-686-07	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	0 1/3 1/2 0 17		
2	NDC:69842-686-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	0 1/3 1/2 0 17		
3	NDC:69842-686- 60	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	10/01/2018		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206214	0 1/3 1/2 0 17	

## **Registrant** - TIME CAP LABORATORIES, INC (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	manufacture(69842-686)	

Revised: 5/2018 CVS HEALTH CORP