

**LORATADINE- loratadine capsule, liquid filled**  
**TIME CAP LABORATORIES INC**

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**TCL 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.

ANTI-HISTAMINE

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

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.

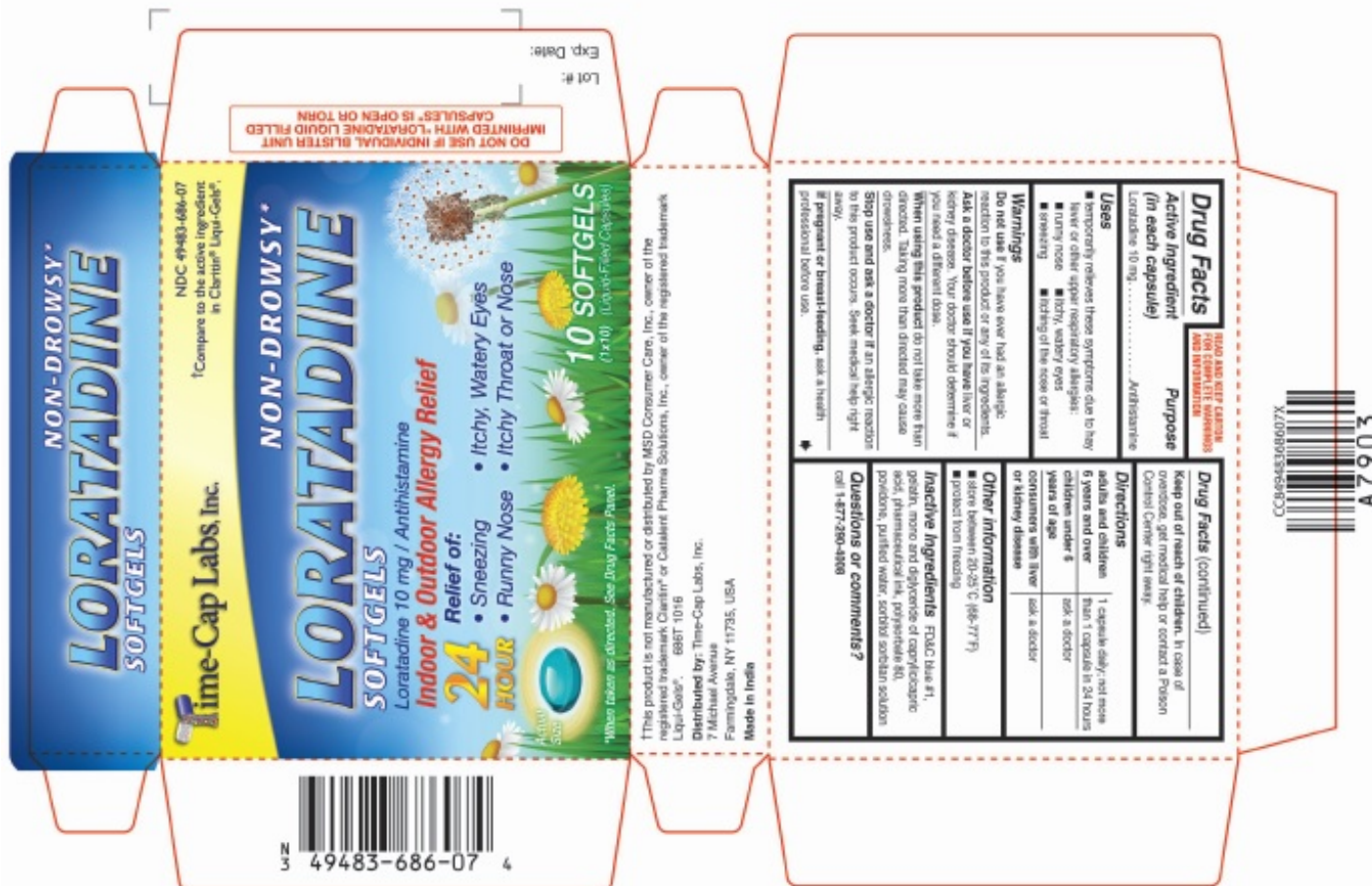
CHILDREN UNDER 6 YEARS OF AGE: ASK A DOCTOR.

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, PHARMACEUTICAL INK, POLYSORBATE 80, POVIDONE, PURIFIED WATER, SORBITOL SORBITAN SOLUTION.



## LORATADINE

loratadine capsule, liquid filled

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:49483-686 |
| 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 |
|--|----------|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                   |          |
| GELATIN (UNII: 2G86QN327L)                           |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)                    |          |
| POVIDONE (UNII: FZ989GH94E)                          |          |
| WATER (UNII: 059QF0K00R)                             |          |
| SORBITOL (UNII: 506T60A25R)                          |          |
| CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q218C85) |          |

## Product Characteristics

|                 |      |                     |          |
|-----------------|------|---------------------|----------|
| <b>Color</b>    | blue | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL | <b>Size</b>         | 3mm      |
| <b>Flavor</b>   |      | <b>Imprint Code</b> | 21       |
| <b>Contains</b> |      |                     |          |

## Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:49483-686-07 | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | 10/13/2016           |                    |
| 2 | NDC:49483-686-30 | 30 in 1 BLISTER PACK; Type 0: Not a Combination Product | 10/13/2016           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA206214                               | 10/13/2016           |                    |

**Labeler** - TIME CAP LABORATORIES INC (037052099)

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

## Establishment

| Name                    | Address | ID/FEI    | Business Operations    |
|-------------------------|---------|-----------|------------------------|
| MARKSANS PHARMA LIMITED |         | 925822975 | manufacture(49483-686) |

Revised: 5/2018

TIME CAP LABORATORIES INC