LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, film coated, extended release Target Corporation

Drug Facts

ACTIVE INGREDIENTS (IN EACH TABLET)

Loratadine, USP 10 mg

Pseudoephedrine sulfate, USP 240 mg

PURPOSE

Antihistamine

Nasal decongestant

USES

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - sneezing
 - itchy, watery eyes
 - runny nose
 - itching of the nose or throat
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily restores freer breathing through the nose

WARNINGS

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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.
- symptoms do not improve within 7 days or are accompanied by a fever
- nervousness, dizziness or sleeplessness occurs

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

• do not divide, crush, chew or dissolve the tablet

	1 tablet daily with a full glass of water; not more than 1 tablet in 24 hours
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

OTHER INFORMATION

- **sodium:** contains 10 mg/tablet
- **calcium:** contains 25 mg/tablet
- TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.
- store between 20° C to 25° C (68° F to 77° F).
- protect from light and store in a dry place

INACTIVE INGREDIENTS

Calcium carbonate, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, sodium alginate, sodium citrate, talc and titanium dioxide

QUESTIONS?

Call 1-800-910-6874

PRINCIPAL DISPLAY PANEL

NDC 11673-165-22

non-drowsy**

allergy and congestion relief

pseudoephedrine sulfate, USP 240 mg/nasal decongestant

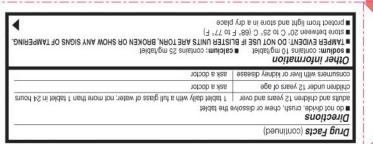
loratadine, USP 10 mg/antihis tamine

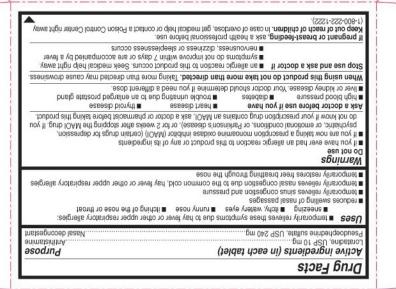
indoor & outdoor allergies

Compare to active ingredients in Claritin-D[®]24 Hour*

up & upTM
extended-release tablets, 24-hour relief
of nasal and sinus congestion due to
colds or allergies, sneezing/runny nose/
itchy, watery eyes/itchy throat or nose due to allergies
original prescription strength
***when taken as directed
see drug facts panel
15 TABLETS
Distributed by Target Corporation
5079462/R0710









LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-165
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg		
PSEUDO EPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDO EPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE SULFATE	240 mg		

Inactive Ingredients				
Ingredient Name	Strength			
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)				
COLLOIDAL SILICON DIO XIDE (UNII: ETJ7Z6XBU4)				
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
PO VIDO NE (UNII: FZ989 GH94E)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SHELLAC (UNII: 46 N107B71O)				
SODIUM ALGINATE (UNII: C269C4G2ZQ)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

Product Characteristics			
Color	white (White to Off-White)	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	RX724
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-165-52	10 in 1 BLISTER PACK		
2	NDC:11673-165-22	15 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076557	11/17/2004	

Labeler - Target Corporation (006961700)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories Inc.		051565745	manufacture(11673-165)	

Revised: 10/2012 Target Corporation