LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, coated
Dr. Reddy's Laboratories Inc.

Levocetirzine Dihydrochloride Tablets USP, 5 mg

Active ingredient (in each tablet)

Levocetirizine dihydrochloride USP, 5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use

- if you have kidney disease
- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine

Ask a doctor before use if you have

- ever had trouble urinating or emptying your bladder

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask doctor if

- you have trouble urinating or emptying your bladder
- an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:

- if breast-feding: not recommended
- if pregnant: 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 65 years of age and older	• ask a doctor
adults and children 12-64 years of age	• take 1 tablet (5 mg) once daily in the evening • do not take more than 1 tablet (5 mg) in 24 hours • 1/2 tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms
children 6-11 years of age	• take 1/2 tablet (2.5 mg) once daily in the evening • do not take more than 1/2 tablet (2.5 mg) in 24 hours
children under 6 years of age	• do not use
consumers with kidney disease	• do not use

Other information

- store between 20° and 25°C (68° and 77°F)
- (bottles only) safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing
- (blister only) safety sealed: do not use if seal is broken or if individual blister unit is open or torn

Inactive ingredients

colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions or comments?

Call **1-888-375-3784**

Levocetirizine Dihydrochloride Tablets, USP 5 mg carton label

Dr. Reddy's
NDC 43598-735-35

Original Prescription Strength

Levocetirizine
Dihydrochloride
Tablets USP, 5 mg
Antihistamine

ALLERGY

24 HOUR

Relief of:

- Sneezing
- Runny Nose
- Itchy Nose or Throat

- Itchy, Watery Eyes

35 Tablets

Levocetirizine Dihydrochloride Tablets USP, 5 mg bottle label

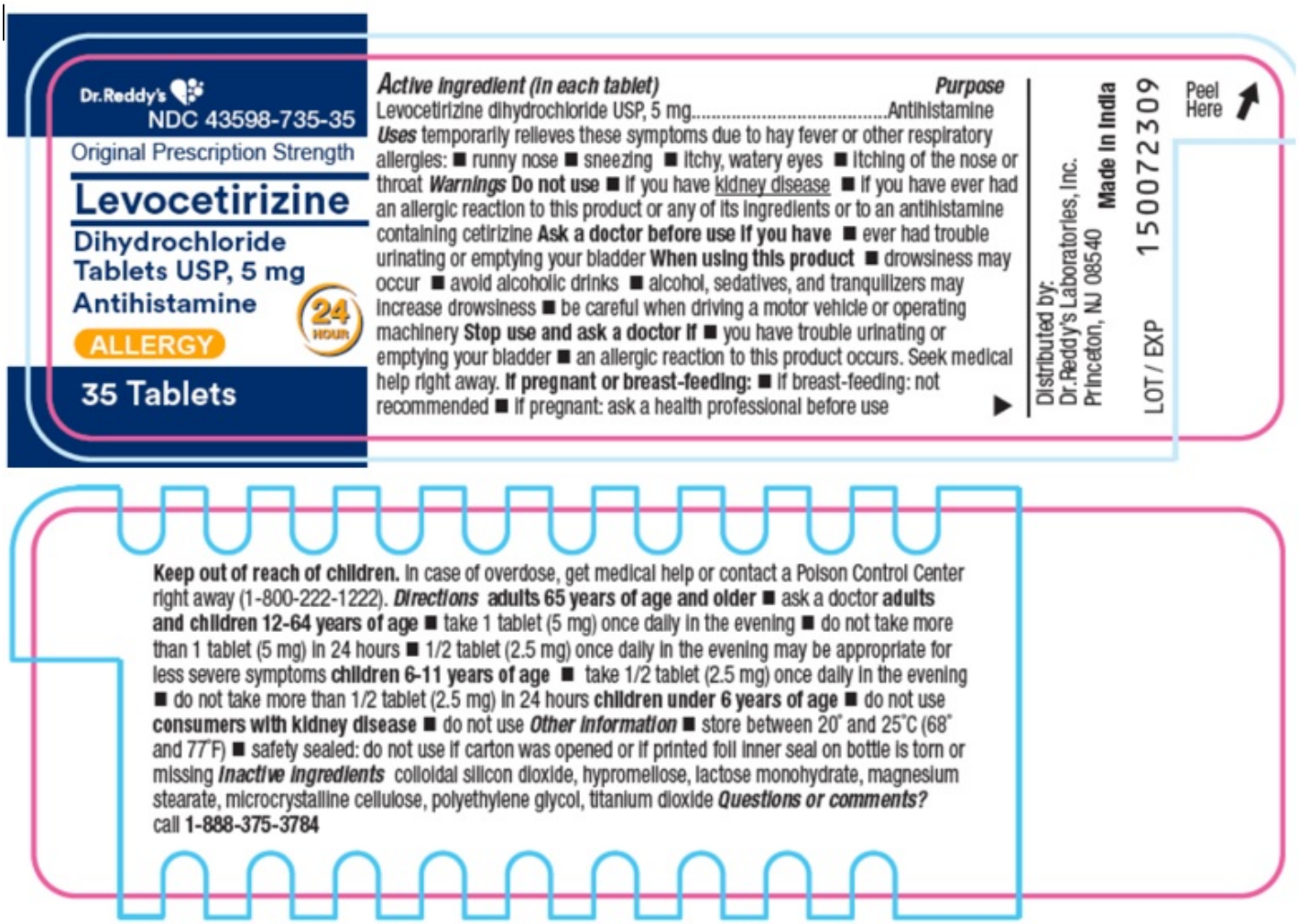
NDC 43598-735-35
Dr.Reddy's

Original Prescription Strength
Levocetirizine
Dihydrochloride Tablets USP, 5 mg
Antihistamine

ALLERGY

24 HOUR

35 Tablets



LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43598-669
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
levocetirizine dihydrochloride (UNII: SOD6A38AGA) (levocetirizine - UNII:6U5EA9RT2O)	levocetirizine dihydrochloride	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	9mm
Flavor		**Imprint Code**	L;L
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-669-35	1 in 1 CARTON	03/12/2018	09/06/2019
1		35 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-669-22	1 in 1 CARTON	03/12/2018	09/06/2019
2		55 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:43598-669-80	1 in 1 CARTON	03/12/2018	09/06/2019
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210375	03/12/2018	09/06/2019

LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43598-735
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
levocetirizine dihydrochloride (UNII: SOD6A38AGA) (levocetirizine - UNII:6U5EA9RT2O)	levocetirizine dihydrochloride	5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	9mm
Flavor		**Imprint Code**	L
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43598-735-35	1 in 1 CARTON	03/12/2018	
1		35 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-735-22	1 in 1 CARTON	03/12/2018	
2		55 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:43598-735-80	1 in 1 CARTON	03/12/2018	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:43598-735-79	2 in 1 CARTON	04/17/2018	
4		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210375	03/12/2018	

Labeler - Dr. Reddy's Laboratories Inc. (802315887)

Establishment

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited-FTO 3		918608162	analysis(43598-669, 43598-735) , manufacture(43598-669, 43598-735)

Establishment

Name	Address	ID/FEI	Business Operations
Reed-Lane, Inc.		001819879	pack(43598-669, 43598-735)

Revised: 9/2019 Dr. Reddy's Laboratories Inc.