# ALLERGY RELIEF-D- loratadine and pseudoephedrine sulfate tablet, extended release HEB

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# HEB-Loratadine and Pseudoephedrine sulfate ER tablets

# Active ingredient (in each capsule)

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
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- 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 enlarged prostrate 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 (1-800-222-1222) right away.

#### **Directions**

do not divide, crush, chew or dissolve the tablet

adults and children 12 years 1 tablet daily with a full glass of water; not more than 1 and over tablet in 24 hours children under 12 years of ageask a doctor consumers with liver or kidneyask a doctor disease

#### Other information

- Safety sealed: do not use if individual blister unit is open or torn
- store between 20° to 25°C (68° to 77°F)
- protect from light and store in a dry place

# Inactive ingredients

black iron oxide, colloidal silicon dioxide, dibasic calcium phosphate anhydrous, ethyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, povidone, propylene glycol, shellac

#### **Questions or comments?**

call toll free 1-888-235-2466 (Mon - Fri 9AM - 5PM EST)

#### **KEEP OUTER CARTON FOR COMPLETE**

#### WARNINGS AND PRODUCT INFORMATION

# THIS PRODUCT IS PACKAGED IN A CHILD-RESITANT AND TAMPER EVIDENT PACKAGE.

Do not use if individual blister unit is open or torn.

<sup>†</sup>This product is not manufactured or distributed by the owners of Claritin-D® 24 hour

MADE WITH PRIDE AND CARE FOR H-E-B®, SAN ANTONIO, TX 78204 100%

#### **GUARANTEE**

### promise

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money.

You have our word on it.

# PRODUCT OF INDIA

L0000918-R1024 KD/DRUGS/KTK/25/460/2001

#### 15's carton

Compare to CLARITIN-D® 24 HOUR active ingredients †

NDC 37808-787-35

H.E.B

**Allergy Relief-D** 

Loratadine and Pseudoephedrine Sulfate Exrended-Release Tablets 10 mg/ 240 mg Indoor & Outdoor Allergies

24

Hour

Non-Drowsy\*

Antihistamine/Nasal Decongestant
Original Prescription Strength
15 days of Relief

#### Relief of:

- Nasal and Sinus Congestion Due to Colds or Allergies
- Sneexing Runny Nose Itchy, Watery Eyes
- Itchy Throat or Nose Due to Allergies

#### 15 EXTENDED- RELEASE TABLETS



# **ALLERGY RELIEF-D**

loratadine and pseudoephedrine sulfate tablet, extended release

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<b>Product</b>	Intorm	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37808-787

**Route of Administration** ORAL

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

Inactive Ingredients	
Ingredient Name	Strength
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ 989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	

Product Characteristics				
Color	white (white to off-white)	Score	no score	
Shape	OVAL	Size	18mm	
Flavor		Imprint Code	LPS	
Contains				

Packaging			
# Item Code	n Code Package Description	Marketing Start Date	Marketing End Date
1 NDC:37808-787	37808-787- 2 in 1 CARTON	05/27/2025	
1	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2 NDC:37808-787	37808-787- 3 in 1 CARTON	05/27/2025	
2	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
-	Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218017	05/27/2025	

# **Labeler -** HEB (007924756)

# Registrant - Bionpharma Inc. (079637826)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
RECIPHARM PHARMASERVICES PRIVATE LIMITED		871401927	manufacture(37808-787)	

Revised: 5/2025 HEB