

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

H-E-B® Allergy Relief-D

Drug Facts

| <i>Active ingredients (in each tablet)</i> | <i>Purpose</i> |
|---|-----------------------|
| Loratadine, USP 10 mg | Antihistamine |
| Pseudoephedrine sulfate, USP 240 mg | 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

| | |
|--|---|
| adults and children 12 years and over | 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 **1-800-406-7984**

PRINCIPAL DISPLAY PANEL - 10 Tablet Blister Pack Carton

Compare to Claritin-D® 24 Hour active ingredients†

NDC 37808-427-69

H-E-B®

Allergy Relief-D

Loratadine, USP 10 mg/Antihistamine

Pseudoephedrine Sulfate, USP 240 mg/Nasal Decongestant

Indoor & Outdoor Allergies

Non-Drowsy*

Allergy & Congestion

Original Prescription Strength

24

Hour

24 Hour Relief of:

- **Nasal & Sinus Congestion Due to Colds or Allergies**
- **Sneezing; Runny Nose; Itchy, Watery Eyes;
Itchy Throat or Nose Due to Allergies**

10 EXTENDED-RELEASE TABLETS

*When taken as directed. See Drug Facts Panel.

**actual
size**

LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:37808-427 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| loratadine (UNII: 7AJ03BO7QN) (loratadine - UNII:7AJ03BO7QN) | loratadine | 10 mg |
| pseudoephedrine sulfate (UNII: Y9DL7QPE6B) (pseudoephedrine - UNII:7CUC9DDI9F) | pseudoephedrine sulfate | 240 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| calcium carbonate (UNII: H0G9379FGK) | |
| silicon dioxide (UNII: ETJ7Z6XBU4) | |
| hydroxypropyl cellulose, unspecified (UNII: 9XZ8H6N6OH) | |
| hypromellose, unspecified (UNII: 3NXW29V3WO) | |
| ferrosoferric oxide (UNII: XM0M87F357) | |
| lactose monohydrate (UNII: EWQ57Q8I5X) | |
| magnesium stearate (UNII: 70097M6I30) | |
| microcrystalline cellulose (UNII: OP1R32D61U) | |
| polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A) | |
| povidone, unspecified (UNII: FZ989GH94E) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| sodium alginate (UNII: C269C4G2ZQ) | |
| sodium citrate, unspecified form (UNII: 1Q73Q2JULR) | |
| talc (UNII: 7SEV7J4RIU) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:37808-427-69 | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | 02/01/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA076557 | 02/01/2018 | |

Labeler - HEB (007924756)

Revised: 5/2018

HEB