LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, extended release
WAL-MART STORES, INC

Loratadine and Pseudoephedrine Sulfate

Drug Facts

Active ingredients (in each tablet)	Purpose
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**

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716

PRINCIPAL DISPLAY PANEL - 15 Tablet Bottle Carton

equate™

NON-DROWSY*
Allergy Relief &
Nasal Decongestant
Loratadine, USP 10mg/Antihistamine
Pseudoephedrine Sulfate,
USP 240mg/Nasal Decongestant
INDOOR AND OUTDOOR ALLERGIES
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

Original prescription strength
*When taken as directed. See Drug Facts Panel.

NDC 49035-488-15

Compare to
Claritin-D® 24Hr
active ingredients**

24
HOUR

Actual Size

15
EXTENDED-
RELEASE
TABLETS

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Loratadine, USP 10 mg ..... Antihistamine

Pseudoephedrine sulfate, USP 240 mg ..... Nasal decongestant

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  - itching of the nose or throat
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Drug Facts (continued)

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- 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 (1-800-222-1222), right away.

Directions

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Drug Facts (continued)

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- 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 1-888-287-1915

Keep the carton. It contains important information. See end panel for expiration date.

Satisfaction guaranteed—Or we'll replace it or give you your money back, or questions or comments please call 1-888-287-1915.

DISTRIBUTED BY: Walgreen Co., Deerfield, IL 60015
PRODUCT OF U.S.A.
This product is not affiliated with the makers/owners of Claritin-D®.

Expiration Date:

Batch No.

NDC 49035-488-15

Compare to Claritin-D® 24Hr active ingredients*

equate™

NON-DROWSY*

Allergy Relief & Nasal Decongestant

Loratadine, USP 10mg/Antihistamine

Pseudoephedrine Sulfate, USP 240mg/Nasal Decongestant

24 HOUR

15 EXTENDED-RELEASE TABLETS

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

Original prescription strength
*When taken as directed. See Drug Facts Panel

INDOOR AND OUTDOOR ALLERGIES

Actual Size

equate™

NON-DROWSY*

Allergy Relief & Nasal Decongestant

24 HOUR

15 EXTENDED-RELEASE TABLETS

LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-488
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	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)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	RX724
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49035-488-15	15 in 1 CARTON; Type 0: Not a Combination Product	06/15/2020	
2	NDC:49035-488-69	10 in 1 CARTON; Type 0: Not a Combination Product	06/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076557	06/15/2020	

Labeler - WAL-MART STORES, INC (051957769)

Registrant - Sun Pharmaceutical Industries, Inc. (139261648)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries, Inc.		139261648	MANUFACTURE(49035-488)

Revised: 6/2020 WAL-MART STORES, INC