LORATADINE AND PSEUDOEPHEDRINE SULFATE- loratadine and pseudoephedrine sulfate tablet, film coated, extended release
Safeway 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 **1-888-723-3929**

DISTRIBUTED BY
BETTER LIVING BRANDS LLC
P.O. BOX 99, PLEASANTON, CA
94566-0009

PRINCIPAL DISPLAY PANEL - 10 Tablet Blister Pack Carton

NDC 21130-724-69

Signature
care™
Quality Guaranteed

24 HOUR | ORIGINAL PRESCRIPTION STRENGTH
Allergy Relief &
Nasal Decongestant
Loratadine, USP 10 mg/Antihistamine
Pseudoephedrine Sulfate, USP 240 mg/
Nasal Decongestant

Actual Size

Compare to
Claritin-D®
24 Hour
active ingredients†

- Indoor & outdoor allergies
- Non-drowsy*
- Relief of:
  Nasal & sinus congestion due to colds
  or allergies

Sneezing; runny nose; itchy,watery eyes;
itchy throat or nose due to allergies

*When taken as directed. See Drug Facts Panel.

10 EXTENDED-RELEASE TABLETS

NDC 21130-724-69

Signature care™

Quality Guaranteed

24 HOUR | ORIGINAL PRESCRIPTION STRENGTH

Allergy Relief & Nasal Decongestant

Loratadine, USP 10 mg/Antihistamine
Pseudoephedrine Sulfate, USP 240 mg/
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Compare to Claritin-D® 24 Hour active ingredients†

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10 EXTENDED-RELEASE TABLETS

†All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Claritin-D®.

Batch No.: Expiration Date:

Non Varnish Area

OUR PROMISE 100% GUARANTEED

DISTRIBUTED BY
BETTER LIVING BRANDS LLC
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94566-0009
1-888-723-3929
www.betterlivingbrandsLLC.com R0615

RD 15154 S3289

3 21130 76209 6

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

Drug Facts (continued)

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Drug Facts (continued)

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Loratadine, USP 10 mg ..... Antihistamine
Pseudoephedrine sulfate, USP 240 mg ..... Nasal decongestant

5118098

5118098

LORATADINE AND PSEUDOEPHEDRINE SULFATE

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21130-724
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: 3WQ0SDW1A)	
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 (White to Off-White)	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	RX724
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:21130-724-69	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/17/2004	
2	NDC:21130-724-15	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/17/2004	

Marketing Information

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

Labeler - Safeway Inc. (009137209)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	MANUFACTURE(21130-724)

Revised: 12/2021 Safeway Inc.