

**LORATADINE D- loratadine, pseudoephedrine sulfate tablet, film coated, extended release**  
**Sportpharm LLC**

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**Loratadine-D 12 Hour Drug Facts**

**Active ingredients (in each tablet)**

Loratadine 5 mg

Pseudoephedrine sulfate 120 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 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 every 12 hours; not more than 2 tablets in 24 hours
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

**Other information**

- **each tablet contains:**calcium 25 mg
- do not use if blister unit is broken or torn
- store between 20° to 25°C (68° to 77°F)
- keep in a dry place

**Inactive ingredients**

croscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, pharmaceutical ink, povidone, titanium dioxide

**Questions or comments?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

Relabeled For:



Loratadine-D (Pseudoephedrine Sulfate + Loratadine)

NDC: 85766-047-10

Qty: 10

Manufactured For: Padagis

Source NDC: 45802-122-46

Description: white to off-white/round/7U0 Pseudoephedrine Sulfate 120 mg/Loratadine 5 mg ER Tablets

Lot #: XXXXXXXX

Exp:

Batch #: XXXXXXXX

Drug Status: OTC



(01) 0 0385766 04710 1

(17)

(10) XXXXXXXX

(21)

Loratadine-D (Pseudoephedrine Sulfate + Loratadine)

NDC: 85766-047-10

S/N:

Qty: 10

Loratadine-D (Pseudoephedrine Sulfate + Loratadine)

NDC: 85766-047-10

S/N:

Qty: 10

Loratadine-D (Pseudoephedrine Sulfate + Loratadine)

NDC: 85766-047-10

S/N:

Qty: 10

Packaged By: Enochem Pharmaceuticals Torrance, CA 90501  
CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

## LORATADINE D

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85766-047(NDC:45802-122)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LORATADINE</b> (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)	LORATADINE	5 mg
<b>PSEUDOEPHEDRINE SULFATE</b> (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F)	PSEUDOEPHEDRINE SULFATE	120 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white (to off-white)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	7U0
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:85766-047-10	10 in 1 CARTON	08/02/2025	
1		1 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	ANDA076050	04/10/2018	

**Labeler** - Sportpharm LLC (125298538)

Revised: 2/2026

Sportpharm LLC