

**PICNIC NASAL DECONGESTANT AND ANTIHISTAMINE- loratadine,  
pseudoephedrine sulfate tablet, film coated, extended release  
30M One, Inc.**

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**Thirty Madison Inc Nasal Decongestant & Antihistamine 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**

ALLERGY & CONGESTION

picnic

PSEUDOEPHEDRINE SULFATE & LORATADINE

EXTENDED RELEASE TABLETS 120 mg / 5 mg

Nasal Decongestant & Antihistamine

Compare to the active ingredients in Claritin-D<sup>®</sup> 12 hour

Indoor & Outdoor Allergies / Non-Drowsy\*

Relief of: • Nasal and Sinus Congestion Due to Colds or Allergies

• Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose Due to Allergies

Actual Size

12 Hour

\*When taken as directed. See Drug Facts Panel.

20 TABLETS

Send your *symptoms* packing

ALLERGY & CONGESTION

# picnic



PSEUDOEPHEDRINE SULFATE & LORATADINE  
EXTENDED RELEASE TABLETS 120 mg/5 mg

## Nasal Decongestant & Antihistamine

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**Relief of:** • Nasal and Sinus Congestion Due to Colds or Allergies  
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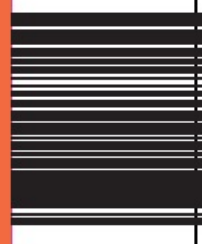


Actual Size

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\*When taken as directed.  
See Drug Facts Panel.

**20 TABLETS**



7U060 TH C1

### Drug Facts

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Pseudoephedrine sulfate 120 mg	Nasal decongestant

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### Drug Facts (continued)

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- 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** crosscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, pharmaceutical ink, polydioxane, titanium dioxide

### Drug Facts (continued)

Questions or comments? 1-800-719-9260

Distributed by:  
Thirty Madison, Inc.  
New York, NY 10001



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# PICNIC NASAL DECONGESTANT AND ANTIHISTAMINE

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80159-301
<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 Date	Marketing End Date
1	NDC:80159-301-03	20 in 1 CARTON	01/04/2022	
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	01/04/2022	

