

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75706

DRAFT FINAL PRINTED LABELING

10/16 GPP 2/21/07

3 21 2003

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> reduces swelling of nasal passages temporarily relieves sinus congestion and pressure temporarily restores freer breathing through the nose 	<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease thyroid disease trouble urinating due to an enlarged prostate gland liver or kidney disease. Your doctor should determine if you need a different dose.
<p>Warnings APPROVED</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 the product. 	<p>When using this product do not take more than directed. Taking more than directed may cause drowsiness.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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

Drug Facts (continued)		Drug Facts (continued)
<p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>		<p>Other information</p> <ul style="list-style-type: none"> ● safety sealed: sealed with printed foil under cap for your protection. ● store between 2° and 25°C (36° and 77°F) ● protect from light and store in a dry place
<p>Directions</p> <ul style="list-style-type: none"> ● do not divide, crush, chew or dissolve the tablet 		<p>Inactive ingredients</p> <p>black iron oxide, candelilla wax powder, colloidal silicon dioxide, glyceryl monostearate, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate 80, propylene glycol, sodium lauryl sulfate, talc and titanium dioxide</p> <p>APPROVED</p>
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 ▶	

ANDA #75-706
 Loratadine & Pseudoephedrine Sulfate
 ER Tablets, 10 mg/240 mg
 Final Printed Labeling



NEW NDA #2037-605-10
 FEB 21 2003

Non-Drowsy*
**LORATADINE AND
 PSEUDOEPHEDRINE SULFATE
 EXTENDED RELEASE TABLETS
 (24 Hour Formulation)**

Loratadine 10 mg/Antihistamine
 Pseudoephedrine Sulfate 240 mg/Nasal Decongestant

For Relief of:
 Nasal and Sinus Congestion
 Sneezing; Runny Nose
 Itchy, Watery Eyes
 Itchy Throat or Nose

Allergy & Congestion

APPROVED

*When taken as directed.
 See Drug Facts Panel.

1000 EXTENDED RELEASE TABLETS

Manufactured by:
 Andrx Pharmaceuticals, Inc.
 Fort Lauderdale, FL 33314

Drug Facts

Active ingredients (In each tablet)

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

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - nasal congestion
 - runny nose
 - sneezing
 - itchy, watery eyes
 - itching of the nose or throat
- 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 the product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.
- thyroid disease
- diabetes

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.

Drug Facts (continued)

- 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.

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

- safety sealed: sealed with printed foil under cap for your protection.
- store between 2° and 25°C (36° and 77°F)
- protect from light and store in a dry place

Inactive ingredients

black iron oxide, candellilla wax powder, colloidal silicon dioxide, glyceryl monostearate, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate 80, propylene glycol, sodium lauryl sulfate, talc and titanium dioxide

7018 (02/03)

LOT #:

EXP:



ANDA #75-706
Loratadine & Pseudoephedrine Sulfate
ER Tablets, 10 mg/240 mg
Final Printed Labeling

	NDC 62037-605-01	Drug Facts	OPEN FOR FULL LABELING
Non-Drowsy*		Active Ingredients (in each tablet) Purpose Loratadine 10 mg.....Antihistamine Pseudoephedrine sulfate 240 mg.....Nasal decongestant	
LORATADINE AND PSEUDOEPHEDRINE SULFATE EXTENDED RELEASE TABLETS (24 Hour Formulation)		Uses	
Loratadine 10 mg/Antihistamine Pseudoephedrine Sulfate 240 mg/Nasal Decongestant		temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ nasal congestion ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat	
For Relief of: Nasal and Sinus Congestion Sneezing; Runny Nose Itchy, Watery Eyes Itchy Throat or Nose	Allergy & Congestion	FEB 21 2003	7019 (02/03)
100 EXTENDED RELEASE TABLETS	*When taken as directed. See Drug Facts Panel.		LOT # EXP:
	APPROVED	N 3 62037-605-01 7	
		Manufactured by: Andrx Pharmaceuticals, Inc. Fort Lauderdale, FL 33314	