LORATADINE AND PSEUDOEPHEDRINE- loratadine and pseudoephedrine sulfate tablet, extended release
Bryant Ranch Prepack

DRUG FACTS

ACTIVE INGREDIENTS (IN EACH TABLET)

Loratadine, USP 10 mg

Pseudoephedrine sulfate, USP 240 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 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.** ***(for blister carton/label)***
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.** ***(for bottle carton/label)***
- 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**

Loratadine/psuedoephedrine 24 Hour tab

LORATADINE AND PSEUDOEPHEDRINE

loratadine and pseudoephedrine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:63629-1330(NDC:51660-724)
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (LORATADINE)	LORATADINE	10 mg
PSEUDOEPHEDRINE SULFATE (PSEUDOEPHEDRINE)	PSEUDOEPHEDRINE SULFATE	240 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE	
SILICON DIOXIDE	
HYDROXYPROPYL CELLULOSE	
HYPROMELLOSES	
FERROSOFERRIC OXIDE	
LACTOSE MONOHYDRATE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOLS	
POVIDONES	
STARCH, CORN	
PROPYLENE GLYCOL	
SHELLAC	
SODIUM ALGINATE	
SODIUM CITRATE	
TALC	

TITANIUM DIOXIDE	

Product Characteristics

Color	white	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	RX724
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-1330-1	14 in 1 BOTTLE		
2	NDC:63629-1330-2	5 in 1 BOTTLE		
3	NDC:63629-1330-3	10 in 1 BOTTLE		
4	NDC:63629-1330-4	15 in 1 BOTTLE		
5	NDC:63629-1330-5	30 in 1 BOTTLE		
6	NDC:63629-1330-6	60 in 1 BOTTLE		
7	NDC:63629-1330-7	20 in 1 BOTTLE		

Marketing Information

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

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-1330), RELABEL(63629-1330)