

**LORATADINE D- loratadine and pseudoephedrine sulfate tablet, extended release
Bryant Ranch Prepack**

Perrigo Loratadine-D 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

Pseudoephedrine/Loratadine 120mg/ 5mg

Packaged by Bryant Ranch

North Hollywood, CA, 91605

Pseudoephedrine /Loratadine 120mg/ 5mg

LOT 53546
FX Only

WHITE ROUND 013

Compare To:

Claritin-D 12 Hour Tablet

Perrigo New York Inc

14

Exp: MM/YY

NDC

6362947901

Keep all drugs out of reach of children
Store at room temp of 20-25 C (68-77F)



04790153546

LORATADINE D

loratadine, pseudoephedrine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:63629-4790(NDC:45802-106)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (LORATADINE)	LORATADINE	5 mg
PSEUDOEPHEDRINE SULFATE (PSEUDOEPHEDRINE)	PSEUDOEPHEDRINE SULFATE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS	
HYPROMELLOSES	
LACTOSE MONOHYDRATE	
MAGNESIUM STEARATE	
POVIDONES	
TITANIUM DIOXIDE	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-4790-1	14 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076050	01/19/2012	

Labeler - Bryant Ranch Prepack (171714327)**Registrant** - Bryant Ranch Prepack (171714327)**Establishment**

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-4790), RELABEL(63629-4790)

Revised: 1/2013

Bryant Ranch Prepack