LORATADINE- loratadine capsule, liquid filled
Bionpharma Inc.

Drug Facts

Active ingredient (in each capsule)

Loratadine 10 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings

Do not use

if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

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.

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

adults and children 6 years and over	1 capsule daily; not more than 1 capsule in 24 hours
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- **Tamper-evident: do not use if foil seal under cap, printed with "Sealed for your protection" is missing, open or broken.** ***(For Bottle Labels and Cartons)***
- **Safety sealed: do not use if individual blister unit printed with Loratadine Capsule, 10 mg is open or torn.** ***(For Blister Carton)***
- store between 20° to 25°C (68° to 77°F)
- protect from freezing

Inactive ingredients

FD&C blue no.1, gelatin, glycerin, hypromellose, hydrolyzed collagen, isopropyl alcohol, mannitol, medium chain mono- & di-glycerides, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

1-888-235-2466

**This product in not manufactured or distributed by Bayer, owner of the registered trademark Claritin® and Catalent Pharma Solutions, Inc, owner of the registered trademark LIQUI-GELS®.

Manufactured for:

Bionpharma Inc.

600 Alexander Road,

Princeton, NJ 08540

Rev # 07/17

Principal Display Panel

NDC 69452-211-03

Compare to the active ingredient in Claritin® Liqui-Gels®**

Original Prescription Strenght

*Non-Drowsy**

Loratadine Capsules, 10 mg

Antihistamine

Indoor & Outdoor Allergies

24 hour

Relief of:

• *Sneezing*

• *Runny Nose*

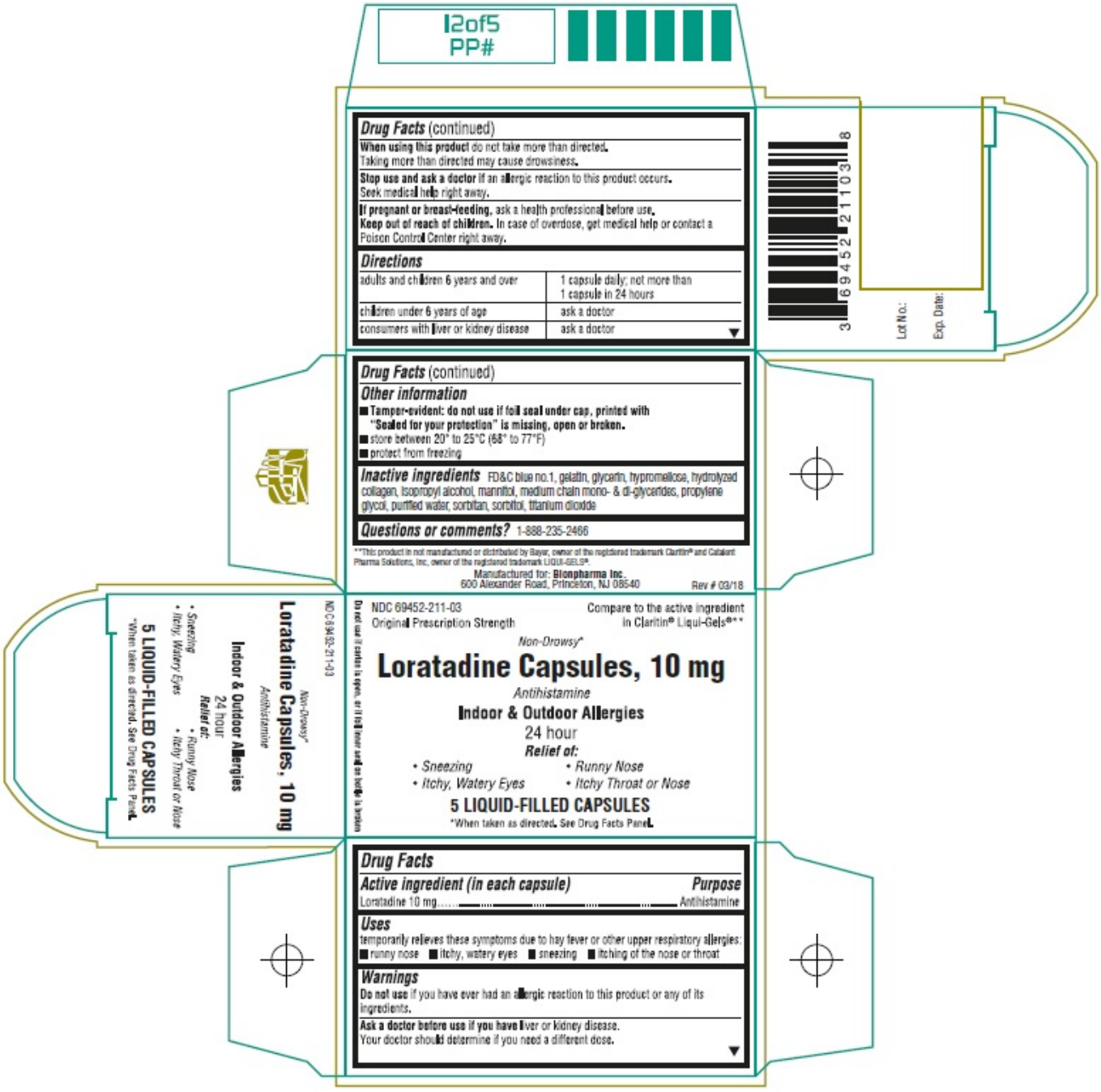
• *Itchy, Watery Eyes*

• *Itchy Throat or Nose*

5 LIQUID-FILLED CAPSULES

*When taken as directed. See Drug Facts Panel

Do not use if carton is open, or if foil inner seal on bottle is broken



LORATADINE

loratadine capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69452-211
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYDROLYSED BOVINE COLLAGEN (ENZYMATIC; 2000-5000 MW) (UNII: 5WE8P977RQ)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MANNITOL (UNII: 3OWL53L36A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	446
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-211-03	1 in 1 CARTON	03/01/2019	
1		5 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69452-211-16	1 in 1 CARTON	03/01/2019	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69452-211-26	1 in 1 CARTON	03/01/2019	
3		200 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69452-211-07	1 in 1 CARTON	03/01/2019	
4		10 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	ANDA202538	03/01/2019	

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations

Patheon Softgels Inc.		002193829	manufacture(69452-211)

Revised: 1/2019 Bionpharma Inc.