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?

call toll free 1-888-235-2466 (Mon - Fri 9AM - 5PM EST)

†This product is not manufactured or distributed by the owners of Claritin® LIQUI-GELS®.

Blister carton contain the following:

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER EVIDENT PACKAGE.
USE ONLY IF BLISTERS ARE INTACT.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Do not use if carton is open, or if individual blister unit is open or torn

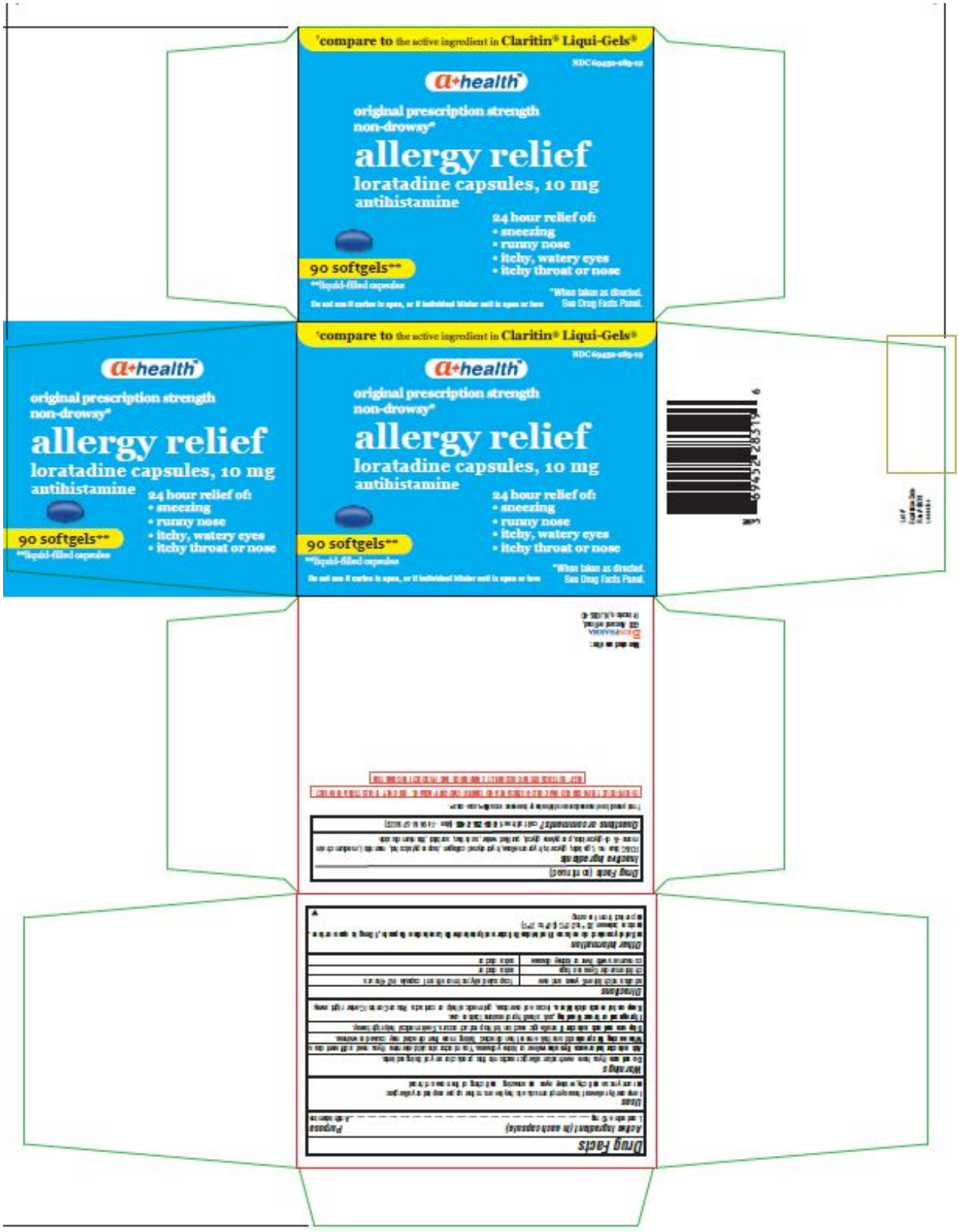
Manufactured for:

Bionpharma Inc.

600 Alexander Road,

Princeton, NJ 08540

Principal Display Panel



LORATADINE

loratadine capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69452-283
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
CAPRYLIC/CAPRIC MONO/DI-GLYCERIDES (UNII: U72Q2I8C85)	
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**	L10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-283-19	1 in 1 CARTON	03/20/2020	
1		90 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69452-283-25	180 in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2020	
3	NDC:69452-283-17	1 in 1 CARTON	08/26/2021	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202538	03/20/2020	

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(69452-283)

Revised: 12/2022 Bionpharma Inc.