

BANOPHEN- diphenhydramine hcl capsule
Bryant Ranch Prepack

0836-Major(100C/1000C)

Active Ingredient (in each banded capsule)

Diphenhydramine Hydrochloride 50 mg

Purpose

Antihistamine

Use

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

- runny nose
- sneezing
- itchy, watery eyes
- itchy throat and nose
- Temporarily relieves these symptoms due to the common cold
 - runny nose
 - sneezing

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist

before use if you are taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

- excitability may occur, especially in children

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

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours

adults and children 12 years of age and over	Take 1 capsule (50 mg)
children under 12 years of age	ask a doctor, the proper dosage strength is not available in this package**

**Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

Other Information

- Store in a dry place at 15° – 30°C (59° – 86°F).
- Do not use if either capsule band or imprinted safety seal under cap is broken or missing
- Protect from moisture
- Contains lactose

Inactive Ingredients

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

Questions?

Questions or comments? 1-800-231-4670

Distributed by: MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

www.majorpharmaceuticals.com

HOW SUPPLIED

NDC: 63629-9451-1: 30 CAPSULES in a BOTTLE

NDC: 63629-9451-2: 60 CAPSULEs in a BOTTLE



GTIN 0083629945115
 Lot 208220
 Exp 5/9/2026
 SN 0123456789

Drug Facts	
Active ingredient (in each banded capsule)	Purpose
Diphenhydramine Hydrochloride 50 mg	Antihistamine
Uses	
Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: •runny nose •sneezing •itchy, watery eyes •itchy throat and nose •Temporarily relieves these symptoms due to the common cold •runny nose •sneezing.	
Warnings	
Do not use •to make a child sleepy •with any other product containing diphenhydramine, even one used on skin. Ask a doctor before use if you have •glaucoma •a breathing problem such as emphysema or chronic bronchitis •trouble urinating due to an enlarged prostate gland. Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers. When using this product •marked drowsiness may occur •avoid alcoholic drinks •alcohol, sedatives, and tranquilizers may increase drowsiness •be careful when driving a motor vehicle or operating machinery •excitability may occur, especially in children. 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.	
Other Information	
•Store at room temperature, USP. •Do not use if either capsule band or imprinted safety seal under cap is broken or missing •Protect from moisture •Contains lactose	
Directions	
•Take every 4-6 hours •Do not take more than 6 doses in 24 hours adults and children 12 years of age and over; Take 1 capsule (50 mg) children under 12 years of age;ask a doctor, the proper dosage strength is not available in this package** **Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.	
Inactive Ingredients	
D&C Red #26, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.	

NDC 63629-9451-1

Banophen Capsules, USP

50 mg

30 Capsules



Repackaged by:
 Bryant Ranch Prepack, Inc.
 Burbank, CA 91504 USA

Manufactured by:
 Major
 Pharmaceuticals



BANOPHEN

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63629-9451(NDC:0904-5307)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC;836
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-9451-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2022	
2	NDC:63629-9451-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/02/2009	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-9451) , RELABEL(63629-9451)

Revised: 4/2024

Bryant Ranch Prepack