BANOPHEN- diphenhydramine hcl capsule
Bryant Ranch Prepack

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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

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.

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 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

Inactive Ingredients

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

Questions?

Questions or comments? (800) 616-2471

Distributed by

MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233,

Livonia, MI 48152

HOW SUPPLIED

NDC: 71335-0081-1: 15 Capsules in a BOTTLE

NDC: 71335-0081-2: 20 Capsules in a BOTTLE

NDC: 71335-0081-3: 30 Capsules in a BOTTLE

NDC: 71335-0081-4: 10 Capsules in a BOTTLE

NDC: 71335-0081-5: 6 Capsules in a BOTTLE

NDC: 71335-0081-6: 100 Capsules in a BOTTLE

NDC: 71335-0081-7: 90 Capsules in a BOTTLE

NDC: 71335-0081-8: 60 Capsules in a BOTTLE

NDC: 71335-0081-9: 2 Capsules in a BOTTLE

NDC: 71335-0081-0: 12 Capsules in a BOTTLE

Diphenhydramine 50mg Capsule

BANOPHEN

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-0081(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:71335-0081-1	15 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
2	NDC:71335-0081-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2018	
3	NDC:71335-0081-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2018	
4	NDC:71335-0081-4	10 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2019	
5	NDC:71335-0081-5	6 in 1 BOTTLE; Type 0: Not a Combination Product	08/07/2019	
6	NDC:71335-0081-6	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/07/2018	
7	NDC:71335-0081-7	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
8	NDC:71335-0081-8	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	

9	NDC:71335-0081-9	2 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	
10	NDC:71335-0081-0	12 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	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(71335-0081) , RELABEL(71335-0081)

Revised: 2/2022 Bryant Ranch Prepack