BANOPHEN- diphenhydramine hcl tablet, film coated
Major Pharmaceuticals

Rite Aid 44-329

Active ingredient (in each tablet)

Diphenhydramine HCl 25 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
- 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

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the 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 beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution 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

- **do not take more than directed**
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

adults and children 12 years and over	1 to 2 tablets
children 6 to under 12 years	1 tablet
children under 6 years	do not use

Other information

- **each tablet contains:** calcium 30 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- protect from moisture
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, D&C red #27 aluminum lake, dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

(800)-616-2471

Principal Display Panel

MAJOR®

NDC 0904-5551-24

Compare to the active ingredient in
Benadryl® Allergy ULTRATAB® Tablets*

Banophen
Diphenhydramine HCl
25 mg
Antihistamine/Allergy Relief

Relieves
Sneezing, Runny Nose,
Itchy Throat and
Itchy, Watery Eyes

Actual Size

24 Minitabs

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Benadryl® Allergy ULTRATAB® Tablets.
50844 REV0721N32908

Rev. 09/21 M-17 Re-order No. 250050

Distributed by:
MAJOR® PHARMACEUTICALS
Livonia, MI 48152

C8300

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each tablet)	Purpose
Diphenhydramine HCl 25 mg	Antihistamine

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▶

Drug Facts (continued)

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MAJOR®

Banophen

Diphenhydramine HCl 25 mg

B-1212-329-08-R
REV0721N32908

MAJOR®

NDC 0904-5551-24

Compare to the active ingredient in Benadryl® Allergy ULTRATAB® Tablets*

Banophen

Diphenhydramine HCl

25 mg

Antihistamine/Allergy Relief

Relieves
Sneezing, Runny Nose,
Itchy Throat and

Actual Size

24 Minitabs

3 09045 55124 0

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

No print/No varnish
Lot & Exp date

MAJOR®

Banophen

Diphenhydramine HCl 25 mg

Major 44-329

BANOPHEN

diphenhydramine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-5551
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	pink	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	44;329
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5551-24	2 in 1 CARTON	03/02/1990	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-5551-59	1 in 1 CARTON	03/02/1990	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/02/1990	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0904-5551)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-5551) , pack(0904-5551)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0904-5551)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(0904-5551)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0904-5551)

Revised: 11/2024 Major Pharmaceuticals