**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule**
**BANOPHEN- diphenhydramine hcl capsule**
**Major Pharmaceuticals**

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**0835&0836(box unit)-Major**

## Active Ingredient (in each banded capsule)

Diphenhydramine HCl... 25 mg

Diphenhydramine HCl... 50 mg

## Purpose

Antihistamine

## Use

25 MG

- 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

50 MG

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold
  - sneezing
  - runny nose
  - itchy, watery eyes
  - itchy throat and nose

## WARNINGS

### Do not use

25 MG

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

50 MG

- to make a child sleepy
- with any other product containing diphenhydramine, including one applied topically

**Ask a doctor before use if you have**

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

50 MG
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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 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

**25 MG**

| | |
|---|---|
| adults and children 12 years of age and over | 1 to 2 capsules |
| children 6 years to under 12 years of age | 1 capsule |
| children under 6 years of age | do not use this product in children under 6 |

| | |
|---|---|
| | years of age |

**50 MG**

| | |
|---|---|
| adults and children 12 years of age and over | 1 capsule |
| children 6 years to 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 20°C – 25°C (68°F – 77°F); excursions permitted to 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature]
- 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

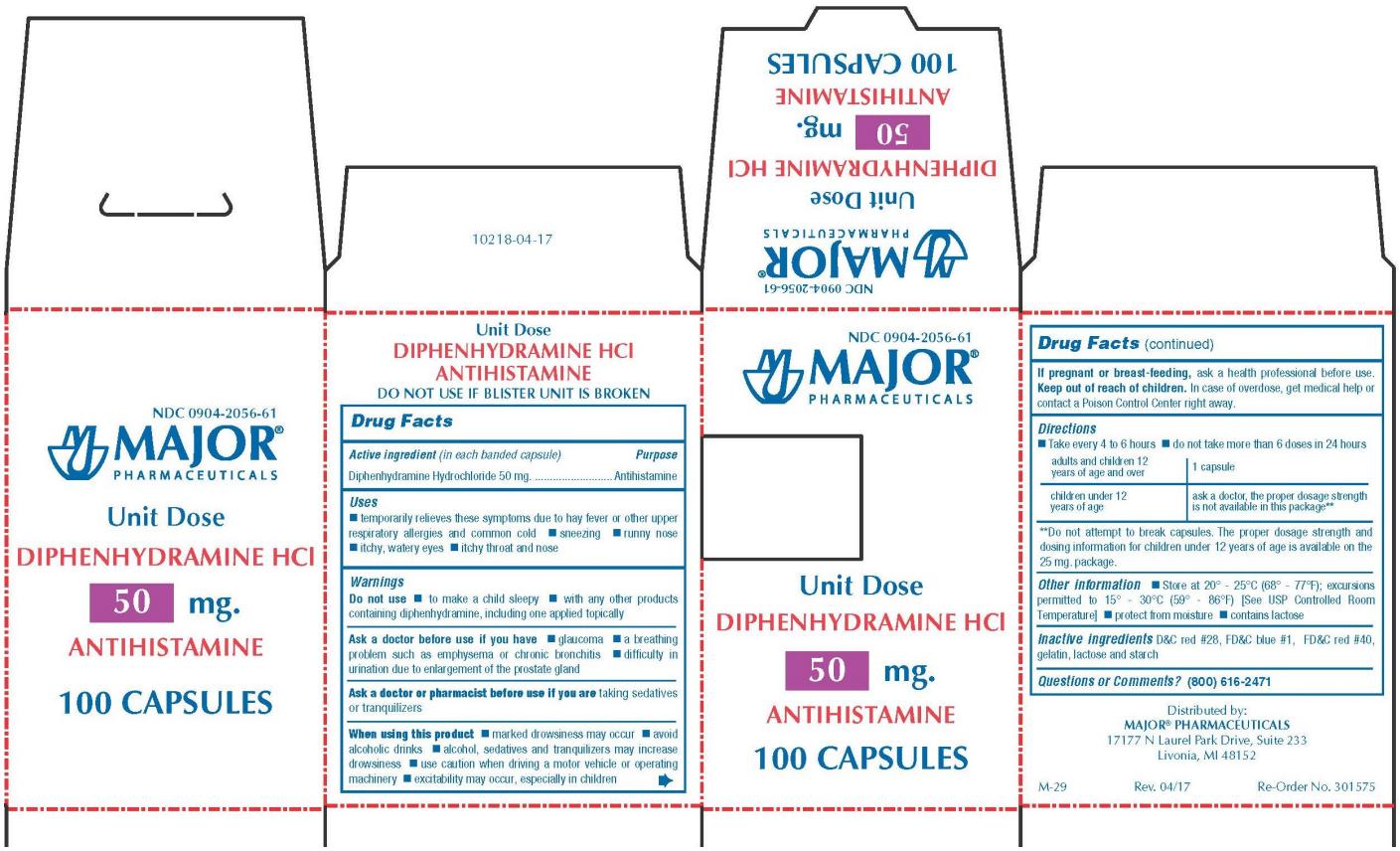
**Distributed by**

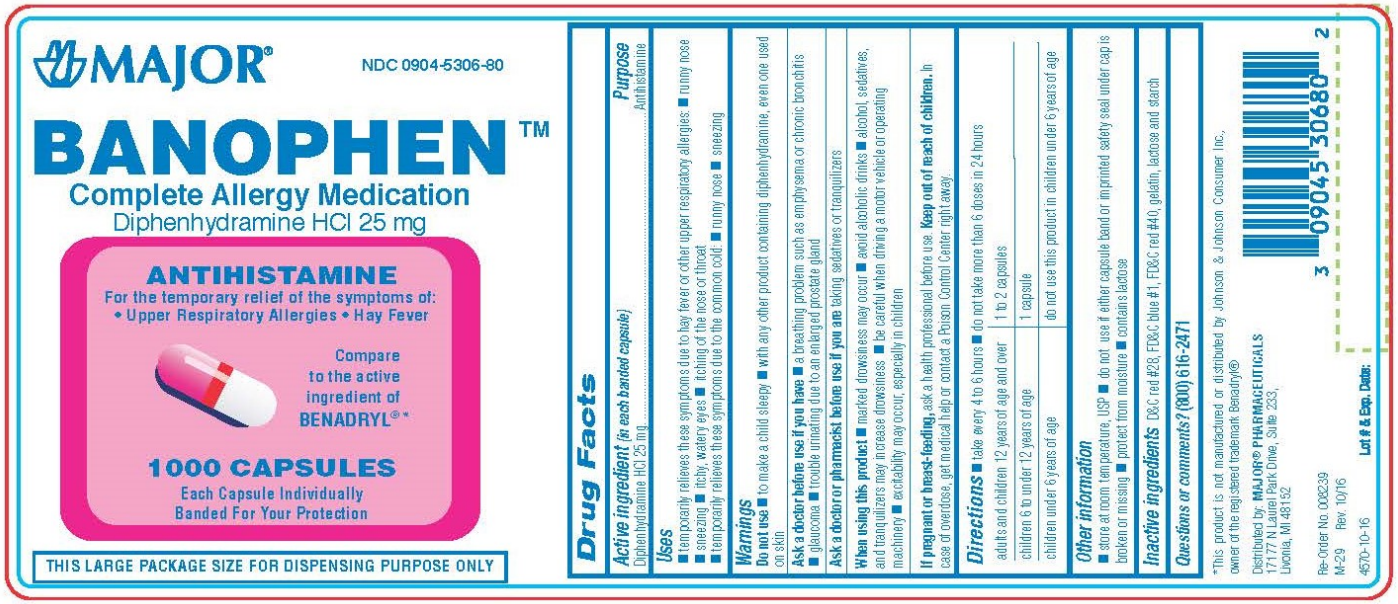
MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233,

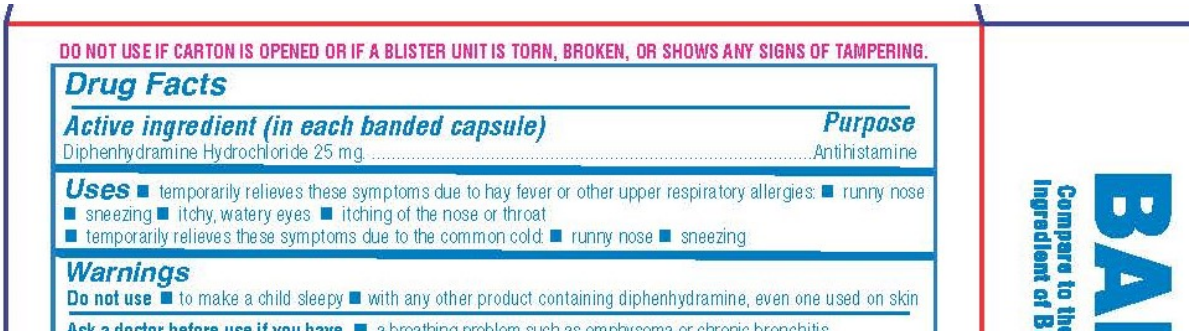
Livonia, MI 48152

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**


10218-04-17
NDC 0904-2056-61
MAJOR PHARMACEUTICALS
Unit Dose
DIPHENHYDRAMINE HCl
50 mg.
ANTIHISTAMINE
100 CAPSULES
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 and common cold ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat and nose
Warnings
Do not use ■ to make a child sleepy ■ with any other products containing diphenhydramine, including one applied topically
Ask a doctor before use if you have ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ 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 drinks ■ alcohol, sedatives and tranquilizers may increase drowsiness ■ use caution when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children
Drug Facts (continued)
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 to 6 hours ■ do not take more than 6 doses in 24 hours
adults and children 12 years of age and over: 1 capsule
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 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature] ■ protect from moisture ■ contains lactose
Inactive ingredients D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose and starch
Questions or Comments? (800) 616-2471
Distributed by:
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
M-29 Rev. 04/17 Re-Order No. 301575


MAJOR®
NDC 0904-5306-80
BANOPHEN™
Complete Allergy Medication
Diphenhydramine HCl 25 mg
ANTIHISTAMINE
For the temporary relief of the symptoms of:
• Upper Respiratory Allergies • Hay Fever
Compare to the active ingredient of BENADRYL®*
1000 CAPSULES
Each Capsule Individually Banded For Your Protection
THIS LARGE PACKAGE SIZE FOR DISPENSING PURPOSE ONLY
Drug Facts
Active ingredient (in each banded capsule) Purpose
Diphenhydramine HCl 25 mg Antihistamine
Uses
■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ 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 ■ 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 to 6 hours ■ do not take more than 6 doses in 24 hours
adults and children 12 years of age and over: 1 to 2 capsules
children 6 to under 12 years of age: 1 capsule
children under 6 years of age: do not use this product in children under 6 years of age
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 or comments? (800) 616-2471
*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark Benadryl®.
Distributed by: MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233,
Livonia, MI 48152
Re-Order No. 008239
M-29 Rev. 10/16
4570-10-16
Lot # & Exp. Date:
3 09045 30680 2

**Major-24BB**


DO NOT USE IF CARTON IS OPENED OR IF A BLISTER UNIT IS TORN, BROKEN, OR SHOWS ANY SIGNS OF TAMPERING.
Drug Facts
Active ingredient (in each banded capsule) Purpose
Diphenhydramine Hydrochloride 25 mg. Antihistamine
Uses ■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ 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
Compare to the

**Ask a doctor before use if you have** ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ 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 to 6 hours ■ do not take more than 6 doses in 24 hours

| | |
|---|---|
| adults and children 12 years of age and over | 1 to 2 capsules |
| children 6 to under 12 years of age | 1 capsule |
| children under 6 years of age | do not use this product in children under 6 years of age |

***Other information*** ■ store at room temperature, USP ■ protect from moisture ■ contains lactose

***Inactive ingredients*** D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose and starch

***Questions or comments?*** (800) 616-2471

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark Benadryl®

Made in the U.S.A. 50844 M-29 Rev. 10/16 4568-10-16

Distributed by: **MAJOR® PHARMACEUTICALS**
17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152

Re-order No. 008237

3 09042 03524 8

**BANOPHEN™**
Compare to the active ingredient of BENADRYL®*
24 CAPSULES

**BANOPHEN™**
Compare to the active ingredient of BENADRYL®*
24 CAPSULES

**BANOPHEN™**
Compare to the active ingredient of BENADRYL®*
24 CAPSULES

**ANTIHISTAMINE**
For the temporary relief from symptoms of:
• Upper Respiratory Allergies • Hay Fever

24 CAPSULES
Each Capsule Individually Banded For Your Protection

Compare to the active ingredient of BENADRYL®*

**BANOPHEN™**
Complete Allergy Medication
Diphenhydramine HCl 25 mg

MAJOR®

NDC 0904-2035-24

**BANOPHEN™**
Compare to the active ingredient of BENADRYL®*
24 CAPSULES

**BANOPHEN™**
Compare to the active ingredient of BENADRYL®*
24 CAPSULES

# DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0904-5306 |
| **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 |
|---|---|
| **D&C RED NO. 28** (UNII: 767IP0Y5NH) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | pink (half pink and half clear with white powder inside) | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | CPC;835 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0904-5306-60 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 01/02/2009 | 07/25/2025 |
| **2** | NDC:0904-5306-80 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 01/02/2009 | |
| **3** | NDC:0904-5306-61 | 10 in 1 BOX | 01/02/2009 | |
| **3** | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **4** | NDC:0904-5306-24 | 2 in 1 CARTON | 03/15/2019 | |
| **4** | | 12 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 |
|---|---|---|---|
| OTC Monograph Drug | M012 | 01/02/2009 | |

# DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0904-2056 |
| **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** (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:0904-2056-61 | 10 in 1 BOX | 01/02/2009 | |
| **1** | | 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 |
|---|---|---|---|
| OTC Monograph Drug | M012 | 01/02/2009 | |

# BANOPHEN

diphenhydramine hcl capsule

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0904-2035 |
| **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 |
|---|---|
| **D&C RED NO. 28** (UNII: 767IP0Y5NH) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | pink (half pink and half clear with white powder inside) | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | CPC;835 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0904-2035-24 | 2 in 1 CARTON | 01/02/2009 | 08/31/2021 |
| **1** | | 12 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 |
|---|---|---|---|
| OTC Monograph Drug | M012 | 01/02/2009 | 08/31/2021 |

## Labeler - Major Pharmaceuticals (191427277)

Revised: 12/2024 Major Pharmaceuticals