

DIPHENHYDRAMINE HCL- diphenhydramine hcl tablet, film coated
Rugby Laboratories

Rugby 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
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- use by expiration date on package

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?

1-800-426-9391

Principal display panel

Rugby®

NDC 0536-1214-29

compare to the active ingredient in Benadryl® Allergy ULTRATABS®*

diphenhydramine HCl

diphenhydramine HCl 25 mg

antihistamine/allergy relief

relieves:

- sneezing • runny nose
- itchy throat
- itchy, watery eyes

100 tablets

actual size

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Benadryl® Allergy ULTRATABS®.
50844 REV0721C32912

Distributed by:

RUGBY® LABORATORIES

Indianapolis, IN 46268

(800) 616-2471

www.major-rugby.com

Rev. 07/25

R-17

Re-order No. 370672



NDC 0536-1214-29

compare to the active ingredient in Benadryl® Allergy ULTRATABS*

diphenhydramine HCl

diphenhydramine HCl 25 mg antihistamine/allergy relief

relieves:

- sneezing • runny nose
- itchy throat
- itchy, watery eyes



actual size

100 tablets**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Drug Facts

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

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PEEL HERE FOR MORE DRUG FACTS

| | |
|--------------------|---|
| STOP PEEING | <p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> a breathing problem such as emphysema or chronic bronchitis glaucoma difficulty in urination due to enlargement of the prostate gland |
| | <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</p> <p>When using this product</p> <ul style="list-style-type: none"> 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 <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> |
| | <p>Directions</p> <ul style="list-style-type: none"> 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 <p>adults and children 12 years and over: 1 to 2 tablets</p> <p>children 6 to under 12 years: 1 tablet</p> <p>children under 6 years: do not use</p> |
| | <p>Other information</p> <ul style="list-style-type: none"> each tablet contains: calcium 30 mg store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) protect from moisture use by expiration date on package |
| | <p>Inactive ingredients</p> <p>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</p> |
| | <p>Questions or comments? 1-800-426-9391</p> |

Rugby 44-329

DIPHENHYDRAMINE HCL

diphenhydramine hcl tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1214 |
| 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: 70097M6I3O) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| 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:0536-1214-29 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/28/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 03/28/2019 | |

Labeler - Rugby Laboratories (079246066)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 038154464 | pack(0536-1214) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|--|
| LNK International, Inc. | | 832867837 | manufacture(0536-1214) , pack(0536-1214) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | manufacture(0536-1214) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | | |
|-------------------------|--|-----------|------------------------|
| LNK International, Inc. | | 868734088 | manufacture(0536-1214) |
|-------------------------|--|-----------|------------------------|

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 967626305 | pack(0536-1214) |

Revised: 9/2025

Rugby Laboratories