

SLEEP TABS- diphenhydramine hcl tablet

Major Pharmaceuticals

Major 44-189

Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin
- for children under 12 years of age

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

avoid alcoholic beverages.

Stop use and ask a doctor if

sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

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**
- adults and children 12 years and over: take 2 tablets at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

Other information

- **each tablet contains:** calcium 60 mg
- protect from moisture
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

Questions or comments?

1-800-426-9391

Principal Display Panel

MAJOR®

NDC 0904-4274-51

compare to the active ingredient in
Original Formula Sominex®*

sleep tabs

diphenhydramine HCl 25 mg
nighttime sleep-aid

actual size

50 tablets

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

*This product is not manufactured or distributed by Medtech
Products Inc., owner of the registered trademark Original Formula
Sominex®. 50844 REV1019P18915

Rev. 07/25 M-17 Re-order No. 700607

Distributed by: **MAJOR® PHARMACEUTICALS**

Indianapolis, IN 46268

(800) 616-2471 www.major-rugby.com

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0904-4274 |
| Route of Administration | ORAL | | |

MAJOR®

NDC 0904-4274-51

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sleep tabs

diphenhydramine HCl 25 mg
nighttime sleep-aid

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MAJOR®

NDC 0904-4274-51

sleep tabs

**KEEP OUTER PACKAGE
FOR COMPLETE PRODUCT
INFORMATION**

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(in each tablet)
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Drug Facts (continued)

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Rev 07/25 M-17 Re-order No. 700607

3 09044 27451 5

No print/No varnish
Lot & Exp date

Major 44-189

| 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 |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

| Product Characteristics | | | |
|-------------------------|-------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | 44;189 |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0904-4274-51 | 1 in 1 CARTON | 04/10/1990 | |
| 1 | | 50 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 | M010 | 04/10/1990 | |

Labeler - Major Pharmaceuticals (191427277)

| Establishment | | | |
|-------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 038154464 | pack(0904-4274) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|--|
| LNK International, Inc. | | 832867837 | manufacture(0904-4274) , pack(0904-4274) |

| Establishment | | | |
|-------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 967626305 | pack(0904-4274) |

| Establishment | | | |
|-------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 117025878 | manufacture(0904-4274) |