**SOMINEX- diphenhydramine hydrochloride tablet, film coated**
**Navajo Manufacturing Company Inc.**

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**Sominex**

***Drug Facts***

**Active Ingredient**

*(in each tablet)*

Diphenhydramine HCl 25 mg

**Purpose**

Nighttime sleep-aid

**Use**

helps reduce difficultly falling asleep

**Warnings**

**Do not use**

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

**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**

- avoid alcoholic beverages
- be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

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

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of accidental overdose get medical help or contact a Poison Control Center right away.

## Directions

**Adults and children 12 years and older:** take 2 tablets at bedtime if needed, or as directed by your doctor

## Other information

- each tablet contains: **calcium 12 mg**
- store at 20º- 25ºC (68º-77ºF)

## Inactive ingredients

cellulose, microcrystalline, croscarmellose sodium, FD&C blue no. 1, hypromellose, lactose monohydrate, light mineral oil, magnesium stearate, silicon dioxide, stearic acid, talc, titanium dioxide, triacetin

## Questions?

**1-866-255-5202** weekdays or visit www.sominex.com

## PRINCIPAL DISPLAY PANEL


| **SOMINEX** |
| --- |
| diphenhydramine hydrochloride tablet, film coated |

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:67751-221(NDC:63029-554) |
| **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 |
|---|---|
| **CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE** (UNII: O7TSZ97GEP) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **LIGHT MINERAL OIL** (UNII: N6K5787QVP) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | blue (Light Blue) | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | S;S |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:67751-221-01 | 1 in 1 CARTON | 06/01/2012 | |
| **1** | | 8 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 | M010 | 06/01/2012 | |

## Labeler - Navajo Manufacturing Company Inc. (091917799)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Navajo Manufacturing Company Inc | | 136941411 | relabel(67751-221) , repack(67751-221) |

Revised: 10/2024 Navajo Manufacturing Company Inc.