

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine
hydrochloride capsule, liquid filled
Gobrand, Inc**

NIGHTTIME

Sleep Aid

Diphenhydramine HCl

Active Ingredient (in each softgel)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

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

Do not use ● for children under 12 years of age ● with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have ● a breathing problem such as asthma, 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, tranquilizers or any other sleep aid

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 overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

take only one dose per day (24 hours)

adults & children 12 years & over

children under 12 years

One dose = TWO 25 mg softgels (50 mg) at bed time if needed or as directed by a doctor
do not use

Other information

- store at 20-25° C (68-77° F)
- avoid excessive heat above 40° C (104° F) and high humidity
- Protect from light

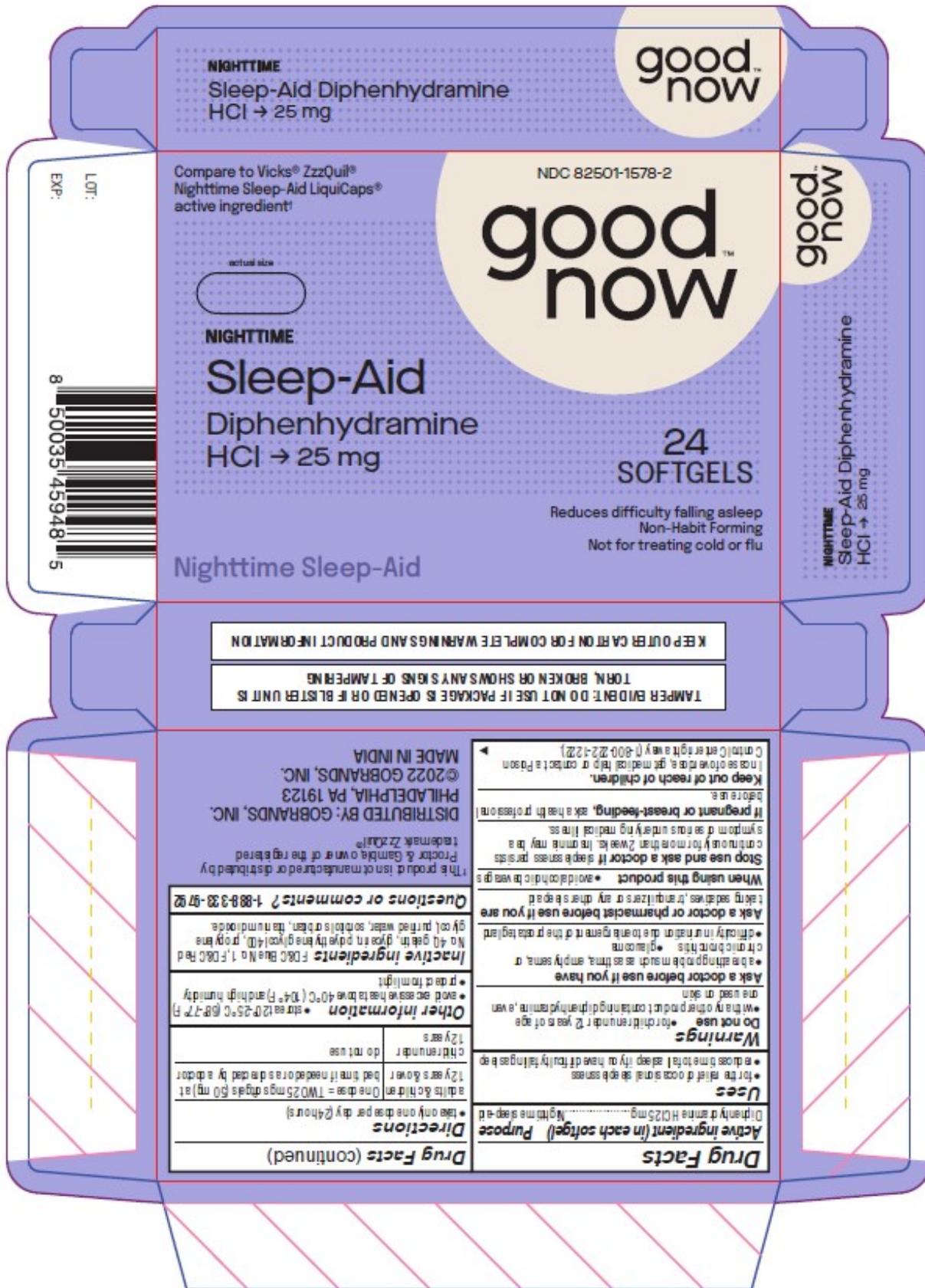
Inactive ingredients

FD&C Blue No. 1, FD&C Red No. 40, gelatin, glycerin, polyethylene glycol 400, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide.

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL



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

KEEP OUT OF REACH OF CHILDREN. SEE BACK OF BOX FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts

Active ingredient (in each softgel) Purpose
 Diphenhydramine HCl 25 mg.....Nighttime sleep-aid

Uses
 • for the relief of occasional sleeplessness
 • dose time to fall asleep if you have difficulty falling asleep

Warnings
 • do not use if you are pregnant or breastfeeding
 • do not use if you are taking sedatives, tranquilizers or any other sleep-aiding medications
 • do not use if you are taking other products containing diphenhydramine, even if used on a different day

Ask a doctor before use if you have
 • a history of asthma, emphysema, or other chronic lung disease
 • a history of urinary retention, enlarged prostate, or other conditions that may affect urination
 • a history of glaucoma
 • difficulty in urinating or other symptoms of urinary retention

Ask a doctor or pharmacist before use if you are
 • taking any other medications, including over-the-counter drugs, prescription drugs, or herbal products
 • pregnant or breastfeeding, or planning to become pregnant or breastfeeding
 • taking any other medications, including over-the-counter drugs, prescription drugs, or herbal products

When using this product • avoid alcohol, grapefruit juice, and other products that may interact with diphenhydramine

Stop use and ask a doctor if sleeplessness persists
 • continuously for more than 2 weeks, the onset may be a symptom of an underlying medical illness

Keep out of reach of children.
 In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Other information • store at 20° to 25°C (68° to 77°F) and excursions permitted to 15° to 30°C (59° to 86°F) • avoid moisture and humidity

Inactive ingredients F&D C Blue No. 1, F&D C Red No. 40, glycerin, polyethylene glycol (400), polyethylene glycol purified water, sorbitol or sorbitan, titanium dioxide

Questions or comments? 1-888-833-9792

Directions
 • take only one dose per day (24 hours)
 One dose = TWO 25 mg softgels (50 mg) at bedtime
 12 years & over: bed time if needed or as directed by a doctor
 12 years & under: do not use

Distributed by: GOBRANDS, INC. PHILADELPHIA, PA 19123
 © 2022 GOBRANDS, INC. MADE IN INDIA

DIPHENHYDRAMINE HYDROCHLORIDE
 diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82501-1578
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	purple	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	602
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82501-1578-2	1 in 1 CARTON	05/16/2022	
1		24 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	05/16/2022	

Labeler - Gobrands, Inc (057499049)**Registrant** - Spirit Pharmaceuticals LLC (179621011)

