EQUALINE NIGHT TIME SLEEP AID- diphenhydramine hcl capsule, liquid filled United Natural Foods, Inc. dba UNFI

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SuperValu Inc. Night Time Sleep Aid Drug Facts

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

Warnings

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 emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to an enlargement of the prostate gland

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 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 yrs & over	2 softgels at bedtime if needed or as directed by a doctor
children under 12 yrs	do not use

Other information

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

Inactive ingredients

edible ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

1-877-932-7948

Package/Label Principal Display Panel

compare to Vicks[®] ZzzQuil[®] active ingredient nighttime sleep-aid diphenhydramine HCI 25mg softgels doctor recommended #1 sleep-aid active ingredient non-habit forming NOT FOR TREATING COLD OR FLU SEE WARNINGS 12 softgels actual size



DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademarks Vicks® ZzzQuil®. #Of U.S. physicians surveyed by an independent market research firm. **GLUTEN FREE**

EƏUALINE[®]

NDC 41163-119-53

Vicks[®] ZzzQuil[®] active ingredient*

compare to

ctual size

nighttime sleep-aid

diphenhydramine HCI 25mg softgels

 doctor recommended #1 sleep-aid active ingredient[‡] non-habit forming

NOT FOR TREATING COLD OR FLU SEE WARNINGS

12 softgels

Drug Facts 05253 EL Active ingredient (in each softgel) Purpose Diphenhy dramin e HCl 25 mg..... ... Nighttime sleep-aid 23 Uses ■ for the relief of occasional sleeplessness ■ reduces time to fall asleep if you have difficulty falling as leep Warnings Like it or let us make it right. That's our quality promise. 877-932-7948 Donot use for children under 12 years of age supervaluprivatebrands.com 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 bionchitis ■ glaucoma ■ difficulty in unination 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 avoid alcoholic beverages 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, as k a health professional before use. Distributed by SUPERVALU INC Eden Prairie, MN 55344 USA 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 on ly one dose per day (24 hours) adults & children 12 yrs & over 2 softgels at bed time if needed or as directed by a doctor children under 12 yrs do not use V

Drug Facts (continued)	Drug Facts (continued)
Other information	Inactive ingredients edible ink, FD&C blue #1,
■ store at 20-25°C (68-77°F)	FD&C red # 40, gelatin, glycerin, polyethylene glycol,
■ avoid excessive heat above 40°C (104°F)	purified water, sorbitd scribitan solution



EQUALINE NIGHT TIME SLEEP AID diphenhydramine hcl capsule, liquid filled **Product Information** NDC:41163-119 **Product Type** HUMAN OTC DRUG Item Code (Source) **Route of Administration** ORAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength DIPHENHYDRAMINE DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) 25 mg (DIPHENHYDRAMINE - UNII:8GTS82S83M) **HYDROCHLORIDE Inactive Ingredients Ingredient Name** Strength FD&C BLUE NO. 1 (UNII: H3R47K3TBD) FD&C RED NO. 40 (UNII: WZ B9127XOA) GELATIN, UNSPECIFIED (UNII: 2G86QN327L) GLYCERIN (UNII: PDC6A3C0OX) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) WATER (UNII: 059QF0K00R) SORBITOL (UNII: 506T60A25R) SORBITAN (UNII: 6092ICV9RU) **Product Characteristics** PURPLE Color Score no score Shape OVAL Size 15mm 052 Flavor **Imprint Code** Contains Packaging **Marketing Start Marketing End** # **Item Code Package Description** Date Date NDC:41163-119- 6 in 1 CARTON 1 03/07/2014 53 2 in 1 BLISTER PACK; Type 0: Not a Combination 1 Product NDC:41163-119- 12 in 1 CARTON 2 03/07/2014 09/30/2021 62 2 in 1 BLISTER PACK; Type 0: Not a Combination 2 Product

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part338	03/07/2014			

Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Revised: 7/2023

United Natural Foods, Inc. dba UNFI