

AXIV - VROZZZ- diphenhydramine hydrochloride capsule, liquid filled
Vivunt Pharma LLC

AXIV VroZzz - Softgels

Drug Facts

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

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 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, consult your doctor. 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

Keep out of reach of children.

Overdose warning

Do not take more than recommended dosage. In case of overdose, get medical help or contact a Poison Control Center. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only 2 softgels per day (24 hours)

adults & children 12 years and over	take 2 softgels at bedtime if needed, or as directed by a doctor
children under 12 years	do not use

Other information

- store between 20-25°C (68-77 °F)
- tamper-evident: Do not use if carton is open or if the foil inner seal is broken or missing.

Inactive ingredients

FD&C Blue No. 1, FD&C Red No. 40, Gelatin, Glycerin, Methylparaben, Polyethylene Glycol 400, Propylparaben, Purified Water, Sorbitol, Titanium Dioxide.

This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark VICKS® ZzzQuil® Nighttime Sleep-Aid LiquidCaps™.

Lic. No.: "DD/DRUGS/DD/416"

Distributed by: Vivunt Pharma LLC

8590 w 74TH Court, Suite 1901

Miami, FL 33156-3178

Made in India

www.vivunt.live

PRINCIPAL DISPLAY PANEL

Compare to VICKS® ZzzQuil®

Nighttime Sleep-Aid LiquidCaps™ active ingredient*

NDC 82706-014-01

AXIV - VroZzz

Sleep Aid

For Nighttime Use

Fast Acting

Non-Habit Forming

Diphenhydramine HCl

72 Softgels** **Liquid-filled capsules

Drug Facts (continued)

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Diphenhydramine HCl 25 mg

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Nighttime Sleep-Aid

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Compare to Vicks® ZzzQuil® Nighttime Sleep-Aid LiquidCaps™
active ingredient
NDC 82706-014-01

72 SOFTGELS**
**Liquid-filled capsules

ACTUAL SIZE

NON-HABIT FORMING
Diphenhydramine HCl

For Nighttime Use
Fast Acting

8 50047 78031 7

Drug Facts (continued)

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Lc. No.: "DD/DHUS/DD/416"

VIVUNT™ 30 YEARS

Distributed by: VIVUNT PHARMA LLC
8501 SW 74th Court, Suite 1901
Miami, FL 33156-8178
Made in India.
www.vivunt.live

AXIV - VROZZZ

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82706-014
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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	purple	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	AXIV
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-014-01	6 in 1 CARTON	03/07/2024	
1		12 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	03/07/2024	

Labeler - Vivunt Pharma LLC (045829437)

Establishment

Name	Address	ID/FEI	Business Operations
SOFTECH PHARMA PRIVATE LIMITED		677111277	manufacture(82706-014)

Revised: 3/2024

Vivunt Pharma LLC