VICKS ZZZQUIL ULTRA- doxylamine succinate tablet The Procter & Gamble Manufacturing Company

Vicks ZzzQuil Ultra

Drug Facts

Active ingredients (in each tablet)

Doxylamine succinate 25 mg

Purpose

Nighttime sleep-aid

Use

helps to reduce difficulty in falling asleep

Warnings

Do not use in children under 12 years of age

Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking any other drugs

When using this product

- avoid alcoholic beverages
- take only at bedtime

Stop use and ask a doctor if

• sleeplessness persists continuously for more than two 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

adults & children 12 years of age and over: take one tablet 30 minutes before going to bed; take once daily or as directed by a doctor

Other information

- store at 68-77° F (20°-25° C)
- retain carton until time of use
- see carton end panel for lot number and expiration date

Inactive ingredients

anhydrous dibasic calcium phosphate, dibasic calcium phosphate dihydrate, FD&C blue no. 1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions?

1-877-881-5813

Tamper Evident:Do not use if blister is opened or torn. If difficult to open, use scissors.

DIST. BY PROCTER & GAMBLE

CINCINNATI OH 45202.

PRINCIPAL DISPLAY PANEL - 24 Tablet Carton

NEW active ingredient.

NEW directions.

Read label.

VICKS ®

ZzzQuil™

ULTRA

NIGHTTIME SLEEP-AID

Doxylamine succinate tablets, 25 mg nighttime sleep-aid

24 TABLETS

From the makers of NyQuil

Clinically tested, proven effective

actual size

1 TABLET

PER DOSE

NEW active ingredient. **NEW directions.** Read label.

NIGHTTIME SLEEP-AID

Doxylamine succinate tablets, 25 mg nighttime sleep-aid



OPEN OTHER END

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www.vicks.com

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Directions

Drug Facts (continued)

VICKS ZZZQUIL ULTRA

doxylamine succinate tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69423-902
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) DOXYLAMINE SUCCINATE 25 mg

Inactive Ingredients		
Ingredient Name	Strength	
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)		
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)		
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)		
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)		

Product Characteristics			
Color	blue	Score	2 pieces
Shape	OVAL	Size	10mm
Flavor		Imprint Code	L441
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69423- 902-12	1 in 1 CARTON	03/01/2021		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:69423- 902-24	2 in 1 CARTON	03/01/2021		
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
3	NDC:69423- 902-48	4 in 1 CARTON	03/01/2021		
3		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
4	NDC:69423- 902-01	1 in 1 POUCH; Type 0: Not a Combination Product	10/16/2023		
5	NDC:69423- 902-32	32 in 1 CARTON	10/16/2023		

, , , ,	, 115, 10 10 10 7	03/01/2021		
ANDA	ANDA040167	03/01/2021		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Marketing Information				
5	1 in 1 POUCH; Type 0: Not a Combination Product			

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 10/2024 The Procter & Gamble Manufacturing Company