CVS NIGHTTIME SLEEP AID- diphenhydramine hydrochloride and acetaminophen liquid
CVS PHARMACY

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.

CVS Nighttime Sleep-aid Pain Reliever

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 1000 mg

Diphenhydramine HCl 50 mg

Purpose

Pain reliever

Nighttime sleep-aid

Uses

- for the temporary relief of occasional minor aches and pains with accompanying sleeplessness.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4 doses (30 mL each) in 24 hrs., which is the maximum daily amount for this product
- taken with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy Alert: Acetaminophen may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- very low sodium

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- avoid alcoholic beverages
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- Sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

These could be signs of a serious condition.

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 at 1-800-222-1222. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

take only one dose (30 mL) per day (24 hours)

Only use dose cup provided

adults & children 12 yrs & over	30 mL at bedtime
children under 12 yrs	do not use

Other information

- **each 30 mL contains:** sodium 10 mg
- store at room temperature

Inactive ingredients

citric acid, flavors, FD&C Blue No. 1, FD&C Red No. 40, glycerin, potassium citrate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose.

Questions or comments?

1-866-467-2748

PRINCIPAL DISPLAY PANEL - 354 ml bottle

Compare to the active ingredient in ZzzQuil™ Night Pain Sleep-Aid*

NDC# 69842-496-12

Nighttime Sleep-Aid

Pain Reliever

Diphenhydramine HCl

Acetaminophen

- Fall Asleep Fast
- Max Strength Pain Reliever
- Non-Habit Forming

Berry Flavor

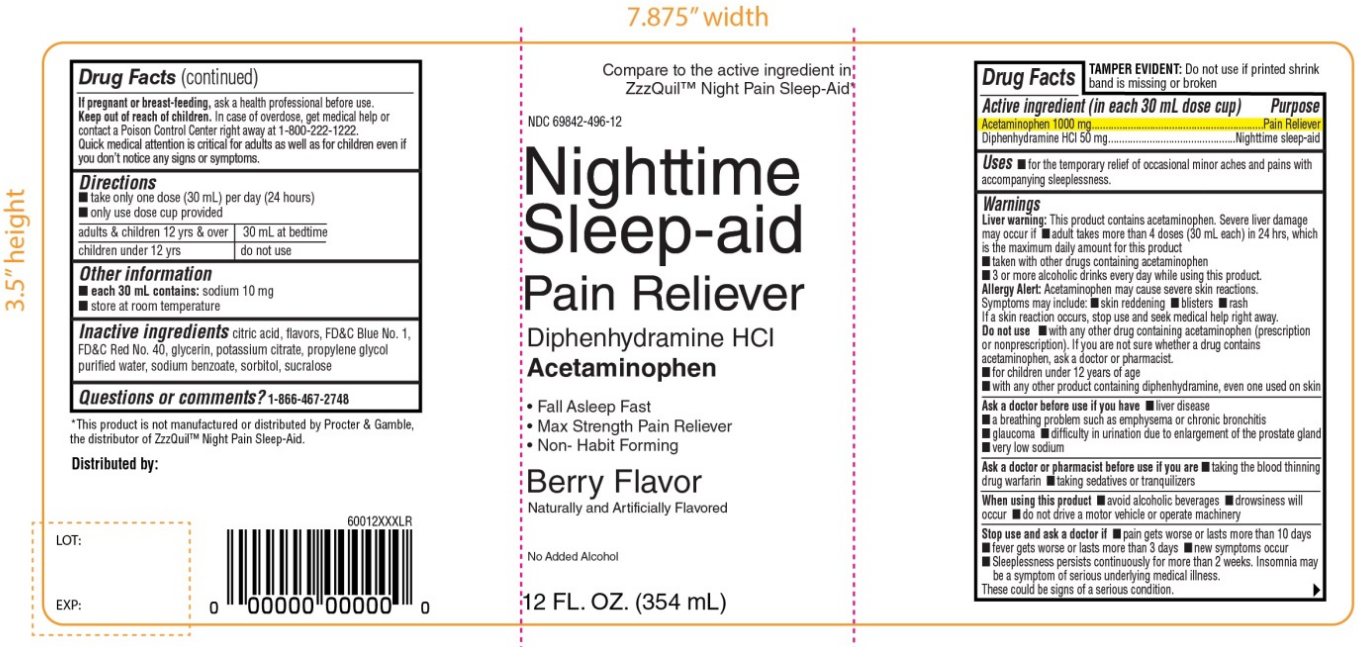
Naturally and Artificially Flavored

No Added Alcohol

12 FL. OZ. (354 ml)

*This product is not manufactured or distributed by Procter & Gamble, the distributor of ZzzQuil™ Nigh Pain Sleep-Aid.

Distributed by:



CVS NIGHTTIME SLEEP AID

diphenhydramine hydrochloride and acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-496
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	1000 mg in 30 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	RED	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-496-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/24/2020	

Labeler - CVS PHARMACY (062312574)