

**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

**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
- very low sodium

### **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 Vicks® ZzzQuil™ Night Pain Sleep-Aid\*

NDC# 69842-448-12

### **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 Vicks® ZzzQuil™ Night Pain Sleep-Aid.

#### **Distributed by:**

**Drug Facts** (continued)

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 the 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  
 very low sodium

**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

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

Distributed by: **CVS Pharmacy, Inc.**  
 One CVS Drive, Woonsocket, RI 02895  
 © 2021 CVS/pharmacy V-30486

LOT:



8001205SLR

EXP:



Compare to the active ingredients in Vicks® ZzzQuil™ Night Pain Sleep-Aid™  
 NDC 69842-448-12

**Nighttime****Sleep Aid & Pain Reliever**

**ACETAMINOPHEN 1000 mg**  
**DIPHENHYDRAMINE HCl 50 mg**

**No Added Alcohol**

- ▶ Fall asleep fast
- ▶ Maximum strength pain reliever
- ▶ Non-habit forming



**Berry Flavor**  
 Naturally & Artificially Flavored

12 FL OZ (354 mL)

**Drug Facts** **TAMPER EVIDENT:** Do not use if printed shrink band is missing or broken

Active ingredients (in each 30 mL)	Purpose
Acetaminophen 1000 mg	Pain reliever
Diphenhydramine HCl 50 mg	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

**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.

**CVS NIGHTTIME SLEEP AID**

diphenhydramine hydrochloride and acetaminophen liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-448
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3Z D4)	

## Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-448-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/12/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/12/2021	

**Labeler** - CVS PHARMACY (062312574)

Revised: 9/2023

CVS PHARMACY