

PAIN AWAY PLUS SLEEP AID - acetaminophen, diphenhydramine hydrochloride liquid 7-Eleven

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.

Drug Facts

Active ingredients

(in each 15 mL)

Acetaminophen USP 500 mg

Diphenhydramine HCl USP 25 mg

Purposes

Pain reliever

Nighttime Sleep Aid

Uses

Temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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.
- with any other product containing diphenhydramine, even one used on skin
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products
- for children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers or any other sleep aid

When using this product

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

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.
- Pain gets worse or lasts more than 10 days
- Fever gets worse or lasts more than 3 days
- Redness or swelling is present
- New symptoms occur

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.

Overdose warning:

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (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

- **do not take more than directed (see overdose warning)**
- **use only enclosed dosing cup** designed for use with this product. Do not use any other dosing device.
- mL = milliliter

adults and children 12 years and over	<ul style="list-style-type: none"> • take 30 mL at bedtime • do not take more than 30 mL in 24 hours
children under 12 years	do not use

Other information

- each 15 mL contains: **sodium 9 mg**

- store between 20-25°C (68-77°F). Do not refrigerate.
- don't use if shrink band is missing or broken
- see back label for lot number and expiration date

Inactive ingredients

anhydrous citric acid, FD&C Blue no.1, FD&C Green no. 3, flavors, high fructose corn syrup, menthol, non-crystallizing sorbitol solution, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium carboxymethylcellulose, and sucralose

Questions or Comments?

1-855-274-4122

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

DISTRIBUTED BY

7-ELEVEN, INC.

IRVING, TX 75063

WWW.7-ELEVEN.COM

Satisfaction Guaranteed 1-800-255-0711

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 8 FL OZ (237 mL Bottle)

24/7 life

BY 7-ELEVENTM

See Warnings Information

Pain Away + Sleep aid

Acetaminophen, Diphenhydramine HCl

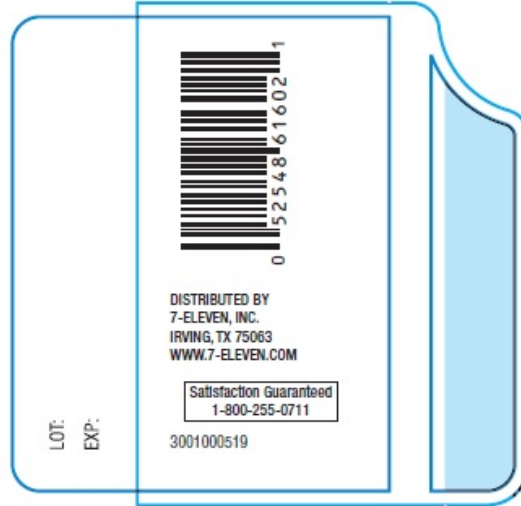
Pain Reliever, Nighttime Sleep Aid

Do not use if printed shrinkband is missing or broken.

8 FL OZ (237 mL) Berry
(Alcohol free)

Flat Label

Base Label



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Diphenhydramine HCl USP 25 mg Nighttime Sleep Aid

Uses
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- 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 redness
- hives
- itching
- swelling of the face, lips, tongue, or throat
- difficulty breathing
- skin 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 non-prescription). If you are not sure, whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
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Drug Facts (continued)

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Questions or comments? Call 1-855-274-4122

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PARENTS:
Learn about teen medicine abuse
WWW.StopMedicineAbuse.org

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Lift Here for Drug Facts

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PAIN AWAY PLUS SLEEP AID

acetaminophen, diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10202-946
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 15 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	BLUE (blue to bluish green)	Score	
Shape		Size	
Flavor	BERRY, PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10202-946-20	1 in 1 CARTON	12/01/2017	
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	12/01/2017	

Labeler - 7-Eleven (007347602)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurohealth LLC		078728447	MANUFACTURE(10202-946)

Revised: 4/2020

7-Eleven