

**ONLY FOR BODY PAIN- acetaminophen, diphenhydramine hcl tablet**  
**O4 Global Trading Usa, Llc**

*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.*

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**Only For - BODY PAIN**

**DRUG FACTS**

**Active ingredient (in each caplet)**

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

**Purpose**

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 1,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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
- in children under 12 years of age
- if you have ever had any allergic reaction to this product or any of its ingredients
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

**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 before use if you are**

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

**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 last 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:** In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions:**

- take with a full glass of water
- **Do not take more than directed (see Overdose Warning)**
- do not take more than 2 caplets in 24 hours

adults and children 12 years of age and over	<ul style="list-style-type: none"> <li>• 2 caplets at bedtime</li> <li>• do not take more than 2 caplets in 24 hours</li> </ul>
children under 12 years of age	do not use

**Other Information:**

- Store at room temperature between 20-25°C (68-77°F).

**Inactive Ingredients:**

Colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1, hydroxypropyl methyl cellulose, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide.

**Questions Or Comments ?**

1-833-665-9444.

NDC: 73006-119-41

**Distributed By:** O4 GLOBAL TRADING USA LLC., 2241 S Watson RD, Suite 121 Arlington, TX 76010.

www.onlyfor.com

**Packaged By:** Strive Pharmaceuticals Inc., East Brunswick, NJ 08816.

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF A BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING.**

**Tear along perforation push product through foil**

### Packaging

**ADULT Only For**  
**PM**  
NDC: 73006-119-41

**ADULT Only For**  
**PM**  
**BODY PAIN  
PAIN RELIEVER  
NIGHTTIME SLEEP AID**

**ACETAMINOPHEN 500mg / Pain Reliever  
Diphenhydramine HCl 25mg / Nighttime sleep aid**

**4 CAPLETS**

3 70692 11941 1

LOT: K006A  
EXP: 06/20

**DRUG FACTS**

Active ingredient (in each caplet)	Purpose
Acetaminophen 500mg	Pain reliever
Diphenhydramine HCl 25 mg	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 1,000 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  
• in children under 12 years of age  
• if you have ever had an allergic reaction to this product or any of its ingredients  
• for more than 10 days for pain unless directed by a doctor  
• for more than 3 days for fever unless directed by a doctor

**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 before use if you are**  
• taking the blood thinning drug warfarin • taking sedatives or tranquilizers

**DRUG FACTS (Continued)**

**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  
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• new symptoms occur.  
These could be signs of a serious condition.

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ask a health professional before use.

**Keep out of reach of children**

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0.337  
Tear along perforation  
push product through foil

www.onlyfor.com CT2DCN4-REV.102018

# ONLY FOR BODY PAIN

acetaminophen, diphenhydramine hcl tablet

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73006-119
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSE 2910 (5 MP.A.S) (UNII: R75537T0T4)	
MAGNESIUM PALMITOSTEARATE (UNII: R4OXA9G5BV)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	blue	Score	no score
Shape	OVAL (Caplet)	Size	12mm
Flavor		Imprint Code	AD01
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73006-119-41	1 in 1 CARTON	03/29/2019	
1		4 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 not final	part343	03/29/2019	

**Labeler** - O4 Global Trading Usa, Llc (081226861)

Revised: 4/2019

O4 Global Trading Usa, Llc