

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.

Only For™ BODY PAIN

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500mg

Diphenhydramine HCl 25mg

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 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
- in 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.

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 WARNINGS: 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">• take 2 caplets at bedtime• do not take more than 2 caplets of this product in 24 hours
children under 12 years of age	<ul style="list-style-type: none">• do not use

Other Information:

- Store at room temperature between 20-25°C (68-77°F).
- avoid excessive heat, cold and humidity.
- close cap tightly after use.

Inactive Ingredients:

colloidal silicon dioxide, croscarmellose sodium, FD&C blue No.1, hydroxy propyl methyl cellulose, magnesium stearate, starch, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide.

Questions or comments?

1-833-665-9444. (Mon-Fri 9am-5pm)

ADULT

PAIN RELIEVER NIGHTTIME SLEEP AID

TAMPER EVIDENT: Do not use if imprinted safety seal under cap is broken or missing

Distributed By: O4 GLOBAL TRADING USA, LLC.

12222 Merit Drive, Suite 1900

Dallas, TX 75251-3209

www.onlyfor.com

Packaged By: Strive Pharmaceuticals Inc.

East Brunswick, NJ 08816.

Packaging


ADULT *Only For.*
25 CAPLETS
 NDC: 73006-120-95
BODY PAIN PAIN RELIEVER NIGHTTIME SLEEP AID
ACETAMINOPHEN 500mg
Diphenhydramine HCl 25mg
 Pain reliever
 Nighttime sleep aid



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 8

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 Lot No. _____
 Exp. Date _____
LIFT HERE

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LB7300611995-REV.00-072020

acetaminophen, diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73006-120
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (LIGHT BLUE)	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	AD01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73006-120-95	1 in 1 CARTON	11/15/2020	
1		25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part343	11/15/2020	

Labeler - O4 Global Trading Usa, Llc (081226861)

Revised: 11/2020

O4 Global Trading Usa, Llc