

**TYLO NIGHT (ACETAMINOPHEN)- acetaminophen tablet, delayed release
America Medic & Science, LLC**

Tylo Night (Acetaminophen)500 mg

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500 mg**

Drug Facts

Active Ingredient

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Night time 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.

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 your 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 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.

Directions

do not take more than directed (see overdose warning).

Adults and children 12 years and over:

- take 2 caplets at bedtime
- do not take more than 2 caplets of this product in 24 hours.

Children under 12 years:

- do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- store between 20-25°C (68-77°F)
- **do not use if neck wrap is broken or missing**
- see end panel for lot number and expiration date

Inactive ingredients

Carnauba Wax, FD&C blue No.1 al lake, FD&C blue No.2 al lake, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Croscarmellose Sodium, Povidone, Crosspovidone, Pregelatinized Starch, Stearic Acid, Titanium Dioxide, Triacetin.

Questions or comments?

call toll free 1-855-470-6722

Package Labeling:

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.

Drug Facts (continued)
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 your 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
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These could be signs of a serious condition.
If pregnant or breast-feeding, ask a health professional before use.
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Do not use
■ with any other drug containing acetaminophen (prescription or nonprescription).
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■ if you have ever had an allergic reaction to this product or any of its ingredients.

FAST RELIEF
TYLO
Night
Non-Habit forming
30 CAPLETS
ACETAMINOPHEN 500mg
Diphenhydramine HCl
Pain Reliever • Nighttime Sleep Aid
Contains No Aspirin

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See New Warnings Information & Directions
NDC 40658-06-30
NEW FOR ADULTS

AMMS
America Medic & Science

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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Manufactured by Elvi Pharma, LLC for America Medic & Science, (AMS), USA
www.AmericaMedic.com

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DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

Lot:
EXP.:

TYLO NIGHT (ACETAMINOPHEN)

acetaminophen tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49638-106
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
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE (UNII: FZ989GH94E)	
CROSPVIDONE (UNII: 2S7830E561)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE (CAPLET)	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49638-106-30	1 in 1 CARTON	07/06/2020	
1		30 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 Drug	M013	07/06/2020	

Labeler - America Medic & Science, LLC (071065464)

Registrant - America Medic & Science, LLC (071065464)

Revised: 2/2024

America Medic & Science, LLC