

**TYLO MIGRAINE (ACETAMINOPHEN)- acetaminophen tablet, delayed release**  
**America Medic & Science, 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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**Tylo Migraine (Acetaminophen)**

**Tylo Migraine (Acetaminophen) 250 mg**

**Drug Facts**

**Active Ingredient**

Acetaminophen 250 mg  
Aspirin 250 mg  
Caffeine 65 mg

**Purpose**

- Ultra relief Migraine pain

**Uses**

- Relieves Migraine

**Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher

- if you are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed.

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

**Do not use**

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription)
- If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

**Ask a doctor before use if you have**

- you have never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest
- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have vomiting with your migraine headache

**Ask a doctor or pharmacist before use if you are**

taking a prescription drug for:

- anticoagulation (thinning of the blood)
- diabetes
- gout
- arthritis
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

**When using this product**

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding
- feel faint
- vomit blood
- have bloody or black stools

- have stomach pain that does not get better
- your migraine is not relieved or worsens after first dose
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occurs

### If pregnant or breast-feeding

### Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away. 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

Drink full glass of water with each dose

- adults and children 12 years and over: take two tablets every 6 hours; not more than 8 tablets in 24 hours
- children under 12 years: ask a doctor

### Other information

- store at controlled room temperature 20°-25°C (68°-77°F)
- read all product information before using. Keep this box for important information.

### Inactive ingredients

Carnauba wax, FD&C blue # 1 al lake, hydroxypropylmethyl cellulose, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid, titanium dioxide

### Questions or comments?

call toll free 1-855-470-6722

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 Aspirin 250 mg, Caffeine 65 mg  
**Purpose** ■ Ultra relief Migraine pain  
**Uses** ■ relieves migraine **Allergy alert:** Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock **Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 8 tablets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product **Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher ■ if you are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed. **Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine



containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat. 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. **Directions:** do not take more than directed ■ Drink full glass of water with each dose ■ adults and children 12 years and over: take two tablets every 6 hours; not more than 8 tablets in 24 hours ■ children under 12 years: ask a doctor **When using this product** Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ you experience any of the following signs of stomach bleeding ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ your migraine is not relieved or worsens after first dose ■ new or unexpected symptoms occur ■ ringing in the ears or loss of hearing occurs **Other information** ■ store at controlled room temperature 20°-25°C (68°-77°F) ■ read all product information before using. Keep this box for important information. **Questions or comments?** call toll free 1-855-470-6722

Manufactured Exclusively for America Medic & Science, (AMS), USA  
[www.AmericaMedic.com](http://www.AmericaMedic.com)

## TYLO MIGRAINE (ACETAMINOPHEN)

acetaminophen tablet, delayed release

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49638-108
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	capsule	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49638-108-30	1 in 1 CARTON	01/17/2019	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part343	01/17/2019	

**Labeler** - America Medic & Science, LLC (071065464)**Registrant** - America Medic & Science, LLC (071065464)

## Establishment

Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc.		037052099	manufacture(49638-108)

Revised: 1/2019

America Medic & Science, LLC