

**TYLO COLD AND FLU NIGHT- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled**  
**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 COLD & FLU (Night)**

***Active ingredients***  
***(in each LiquiCap)***

Acetaminophen 325 mg  
Dextromethorphan HBr 15 mg  
Doxylamine succinate 6.25 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Antihistamine

***Uses***

- temporarily relieves common cold/flu symptoms:
  - cough due to minor throat and bronchial irritation
  - sore throat
  - headache
  - minor aches & pains
  - fever
  - runny nose & sneezing

***Warnings***

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

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Sore throat warning** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**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.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains MAOI, ask a doctor or pharmacist before taking this product.

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

- liver disease

- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland

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

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

**When using this product**

**do not use more than directed.**

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, & tranquilizers may increase drowsiness

**Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

***These could be signs of a serious condition.***

**If pregnant or breast-feeding,**

ask a health professional before use.

**Other Information**

**Keep out of reach of children.**

**Overdose warning** Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

***Directions***

- take only as directed - see Overdose warning
- do not exceed 4 doses per 24 hrs
- adults & children 12 yrs & over: 2 Softgels with water every 6 hrs
- children 4 to under 12 yrs: ask a doctor
- children under 4 yrs: do not use

**when using other Tylo Cold & Flu Day or Night products, carefully read each label to ensure correct dosing**

**Other information:**

store at room temperature

***Inactive ingredients***

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

***Questions?***

**1-855-470-6722**

**TYLO COLD & FLU (Night)**

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg



## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49638-114
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	25mm
Flavor		Imprint Code	SN3;WHITE;INK
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49638-114-12	3 in 1 CARTON	01/17/2019	
1		12 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	01/17/2019	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc.		037052099	manufacture(49638-114)

Revised: 1/2019

America Medic & Science, LLC