

TYLO COLD AND FLU DAY- acetaminophen, dextromethorphan hbr, phenylephrine hcl 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.

TYLO COLD & FLU (Day)

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

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

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

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

- heart disease
- cough that occurs with too much phlegm (mucus)
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product

do not use more than directed.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough get worse or last 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 4 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

FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions?

1-855-470-6722

TYLO COLD & FLU (Day)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49638-113
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	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	25mm
Flavor		Imprint Code	SN2;WHITE;INK
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49638-113-24	2 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	

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(49638-113)

Revised: 1/2019

America Medic & Science, LLC