# NIGHTTIME ULTRA CONCENTRATED COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate softgels capsule, liquid filled WALGREENS

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#### 756T Walgreens Nighttime Ultra concentrated Softgels

#### **Drug Facts**

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# Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 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 & 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 8 softgels in 24 hours, 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

**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

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 an 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, and 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.

**Keep out of reach of children**. 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.

#### **Directions**

• take only as directed

• do not exceed 8 softgels per 24 hrs

adults & children 12 yrs & over children 4 to under 12 yrs children under 4 yrs

2 softgels with water every 4 hrs ask a doctor do not use

#### Other information

store at no greater than 25°C

*Inactive ingredients* D&C yellow no. 10 Al. lake, FD&C blue no. 1 Al. lake, gelatin, glycerin, mica, polyethylene glycol 400, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

#### Questions or comments?Call 1-877-290-4008









# **NIGHTTIME ULTRA CONCENTRATED COLD AND FLU**

acetaminophen, dextromethorphan hbr, doxylamine succinate softgels capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)		

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		

NDC:0363-1756

Inactive Ingredients				
Ingredient Name	Strength			
SORBITAN (UNII: 6092ICV9RU)				
MICA (UNII: V8A1AW0880)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)				
SHELLAC (UNII: 46N107B710)				
WATER (UNII: 059QF0KO0R)				
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)				
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SORBITOL (UNII: 506T60A25R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				

Product Characteristics					
Color	green	Score	no score		
Shape	OVAL	Size	15mm		
Flavor		Imprint Code	152		
Contains					

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-1756- 78	1 in 1 CARTON	07/01/2025	
1		48 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	M012	07/01/2025		

# Labeler - WALGREENS (008965063)

**Registrant -** TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Na me	Address	ID/FEI	<b>Business Operations</b>	
MARKSANS PHARMA LIMITED		925822975	manufacture(0363-1756)	

Revised: 4/2025 WALGREENS