MULTI-SYMPTOM COLD AND FLU RELIEF NIGHTTIME- acetaminophen 325 mg dextromethorphan hbr 15 mg doxylamine succinate 6.25 mg capsule, liquid filled

RITE AID

Multi-Symptom Cold & Flu Relief Nighttime (ACETAMINOPHEN 325 mg DEXTROMETHORPHAN HBr 15 mg DOXYLAMINE SUCCINATE 6.25 mg)

DRUG FACTS

Active ingredients (in each softgel)
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 & 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. Quick medical attention is critical for adults and 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: 2 softgels with water every 6 hrs
- children 4 to under 12 yrs: ask a doctor
- children under 4 yrs: do not use

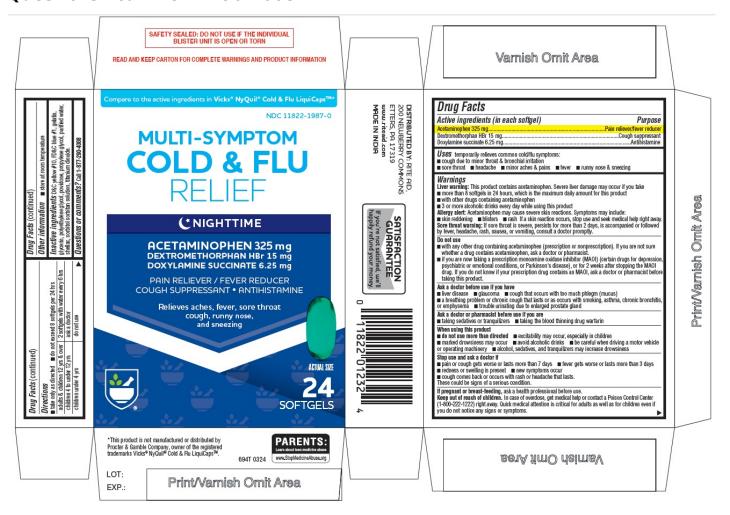
OTHER INFORMATION

Other information

store at room temperature

Inactive ingredients FD&C blue#1, D&C yellow#10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Ouestions? call 1-877-290-4008





MULTI-SYMPTOM COLD AND FLU RELIEF NIGHTTIME

acetaminophen 325 mg dextromethorphan hbr 15 mg doxylamine succinate 6.25 mg capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-1987	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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

GLYCERIN (UNII: PDC6A3C0OX)		
POVIDONE (UNII: FZ 989GH94E)		
WATER (UNII: 059QF0KO0R)		
SHELLAC (UNII: 46N107B710)		
SORBITAN (UNII: 6092ICV9RU)		
GELATIN (UNII: 2G86QN327L)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

Product Characteristics				
Color	green	Score	no score	
Shape	OVAL (OBLONG SHAPED)	Size	21mm	
Flavor		Imprint Code	71	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11822- 1987-0	2 in 1 CARTON	09/15/2021		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:11822- 1987-9	4 in 1 CARTON	09/15/2021		
2		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 Drug	M012	09/15/2021		

Labeler - RITE AID (014578892)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment					
Name	Address	ID/FEI	Business Operations		
MARKSANS PHARMA LIMITED		925822975	manufacture(11822-1987)		

Revised: 4/2024 RITE AID