

NIGHTTIME COLD AND FLU- nighttime cold and flu capsule, liquid filled TARGET CORP

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.

694T Target 11673-976 Nighttime Cold & flu softgels

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 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

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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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

- you get nervous, dizzy or sleepless
- pain, nasal congestion, 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 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

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.

Questions? Call 1-877-290-4008

SAFETY SEALED: DO NOT USE IF THE INDIVIDUAL BLISTER UNIT IS OPEN OR TORN

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Questions? Call 1-877-290-4008
Dist. by Target Corp., Minneapolis, MN 55403
Made in India
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*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® NyQuil® Cold & Flu LiquiCaps®
694T 0720

094 14 059 R01 C-001227-01-095

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Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses ■ temporarily relieves common cold/flu symptoms:
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 ■ sore throat ■ headache ■ minor aches & pains ■ fever ■ runny nose & sneezing

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<p>Drug Facts (continued) Other Information ■ store at room temperature</p>	<p>Compare to active ingredients in Vicks® NyQuil® Cold & Flu LiquiCaps®*</p> <p>nighttime cold and flu nighttime relief</p> <p>acetaminophen (pain reliever/fever reducer) dextromethorphan HBr (cough suppressant) doxylamine succinate (antihistamine)</p> <p>aches fever and sore throat sneezing and runny nose cough</p> <div style="text-align: center;">  <p>24 SOFTGELS</p> </div>
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<p>Drug Facts (continued) Directions ■ take only as directed ■ 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</p>	<p style="text-align: right;">NDC 11673-976-24</p> <p style="text-align: right;">ACTUAL SIZE</p> <p style="text-align: right; font-size: 24px; font-weight: bold;">24</p> <p style="text-align: right;">SOFTGELS</p>
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Lot #: _____

Exp. Date: _____

NIGHTIME COLD AND FLU			
nightime cold and flu capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-976

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-976-24	2 in 1 CARTON	07/08/2020	
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 final	part341	07/08/2020	

Labeler - TARGET CORP (006961700)

Registrant - TIME CAP LABS INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11673-976)

Revised: 11/2022

TARGET CORP