

**COLD AND FLU DAYTIME SEVERE- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl 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.

TARGET DAYTIME COLD AND FLU SEVERE 11673-972

Active ingredients(in each softgel)

Acetaminophen, Phenylephrine HCl,
Dextromethorphan HBr, Guaifenesin

Inactive Ingredients

polyethylene glycol 400, propylene glycol,povidone, shellac, titanium dioxide, gelatin, glycerin, soritol sorbitan solution, FD&C Blue no. 01, FD&C Red No. 40, Purified water

PURPOSE:

- Minor aches and Pains, fever
- Nasal Congestion & Sinus Pressure
- Cough
- Chest Congestion

Uses

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

temporarily relieves common cold/flu symptoms:

nasal congestion

sinus congestion & pressure

cough due to minor throat & bronchial irritation

minor aches & pains

headache

fever

sore throat

reduces swelling of nasal passages

temporarily restores freer breathing through the nose

promotes nasal and/or sinus drainage

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Directions

take only as directed - do not exceed 8 LiquiCaps per 24 hrs - adults & children 12 yrs & over 2 LiquiCaps with water every 4 hrs - children 4 to under 12 yrs ask a doctor ...

take only as directed

do not exceed 8 softgels 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

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 ...

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.

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away. (1800-222-1222)
Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms



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acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-972
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	orange	Score	no score
Shape	BULLET	Size	16mm
Flavor		Imprint Code	73
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-972-16	16 in 1 BLISTER PACK; Type 0: Not a Combination Product	05/29/2020	
2	NDC:11673-972-24	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	05/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part341	05/18/2020	
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Labeler - TARGET CORP (006961700)

Registrant - TIME CAP LABS,INC (037052099)

Establishment			
Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11673-972)

Revised: 5/2020

TARGET CORP