DAYTIME- NIGHTTIME COLD AND FLU- daytime nighttime cold and flu
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 -695T combo DAY-NIGHT COLD AND FLU RELIEF

DAYTIME COLD AND FLU RELIEFDRUG FACTS

DRUG FACTS

Active ingredients (in each softgels)

- Acetaminophen 325 mg
- Dextromethorphan HBr 10 mg
- Phenylephrine HCl 5 mg

Inactive ingredients

FD&C blue 1, FD&C Yellow No. 10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, shellac, purified water, sorbitol sorbitan solution, titanium dioxide

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PURPOSE

- Pain reliever/fever reducer
- Cough suppressant
- Nasal decongestant

Uses
temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever

DIRECTIONS	• take only as directed • do not exceed 4 doses per 24 hours
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

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 & for children even if you do not notice any signs or symptoms.

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

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.

NIGHTIME DRUG FACTS

DRUG FACTS

Active ingredients (in each softgel)

- Acetaminophen 325 mg
- Dextromethorphan HBr 15 mg
- Doxylamine succinate 6.25 mg

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

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sore throat
headache
minor aches & pains
fever

-

Uses

temporarily relieves common cold/flu symptoms: cough due to minor throat & bronchial irritation - sore throat - headache - minor aches & pains - fever - runny nose & sneezing

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- minor aches & pains
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- runny nose & sneezing

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DAYTIME- NIGHTTIME COLD AND FLU

daytime nighttime cold and flu kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11673-969

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11673-969-48	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/08/2020	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	24
Part 2	1 BLISTER PACK	24

Part 1 of 2

DAYTIME COLD AND FLU MULTI SYMPTOM

daytime cold and flu multi symptom capsule, liquid filled

Product Information	
Item Code (Source)	NDC:11673-975
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	

POVIDONE (UNII: FZ989GH94E)	
GELATIN (UNII: 2G86QN327L)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	70
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-975-24	24 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	

Part 2 of 2

NIGHTIME COLD AND FLU

nightime cold and flu capsule, liquid filled

Product Information	
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
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
SHELLAC (UNII: 46N107B71O)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

SORBITOL (UNII: 506T60A25R)	
POVIDONE (UNII: FZ989GH94E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	

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	24 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	

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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(11673-969)

Revised: 7/2020 TARGET CORP