DAY-NIGHT COLD AND FLU- day-night cold 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.

634T TARGET DAY-NIGHT COLD AND FLU RELIEF 11693-947

DAY COLD AND FLU RELIEF

Active ingredients (in each SOFTGEL)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Inactive ingredients: FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Purposes:

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Directions

· do not take more than the recommended dose

· adults and children 12 years and over: take 2 capsules with water

every 4 hours. Do not exceed 10 capsules in 24 hours or as

directed by a doctor.

· children under 12 years: do not use

Pain Reliever-Fever Reducer

Cough Suppressant

Antihistamine

Nasal Decongestant

Nasal Congestion
Headache & Body Ache
Cough
Runny Nose
Sore Throat

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

you take

· more than 4,000 mg of acetaminophen in 24 hours

· with other drugs containing acetaminophen

· 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe

allergic reactions. Symptoms may include:

· skin reddening · blisters · rash · hives

· facial swelling · asthma (wheezing) · shock

If a skin or general allergic 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. 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.

NIGHT COD AND FLU RELIEF

Active ingredeints in each softgel

ACETAMINOPHEN 325 mg

Dextromethorphan Hydrobromide 10 mg

Doxylamine Succinate 6.25 mg

Phenylephrine HCl 5 mg

Inactive ingredients: FD&C Blue #1,gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, , sorbitol sorbitan solution, titanium dioxide

PURPOSE

Pain Reliever-Fever Reducer

Cough Suppressant

Antihistamine

/Nasal Decongestant

DOSAGE & ADMINISTRATION

Directions

· do not take more than the recommended dose

· adults and children 12 years and over: take 2 capsules with water

every 4 hours. Do not exceed 10 capsules in 24 hours or as

directed by a doctor.

· children under 12 years: do not use

Uses

· temporarily relieves these symptoms due to a cold or flu:

· minor aches and pains · headache · cough

· sore throat · nasal and sinus congestion

· temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

· more than 4,000 mg of acetaminophen in 24 hours

· with other drugs containing acetaminophen

· 3 or more aloholic drinks every day while using this product

l Allergy alert: Acetaminophen may cause severe skin or severe

allergic reactions. Symptoms may include:

· skin reddening · blisters · rash · hives

· facial swelling · asthma (wheezing) · shock

If a skin or general allergic 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. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Compare to the active ingredients in Alka-Seltzer Plus® Maximum Strength Cold and Flu Day*

Maximum Strength Daytime

Cold & Flu

Acetaminophen
(Pain Reliever-Fever Reducer)
Dextromethorphan HBr
(Cough Suppressant)
Phenylephrine HCl
(Nasal Decongestant)

Non-Drowsy

- Cough
- Nasal Congestion
- Headache & Body Ache
- Sore Throat
- Sinus Pressure

16 Softgels

Compare to the active ingredients in Alka-Seltzer Plus® Maximum Strength Cold and Flu Night*

Maximum Strength Nighttime

Cold & Flu

Acetaminophen
(Pain Reliever-Fever Reducer)
Dextromethorphan HBr
(Cough Suppressant)
Doxylamine Succinate
(Antihistamine)
Phenylephrine HCl
(Nasal Decongestant)

- Cough
- Nasal Congestion
- Runny Nose
- Headache & Body Ache
- Sore Throat

8 Softgels

24 Total Softgels

DAY-NIGHT COLD AND FLU

day-night cold flu kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11673-947

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11673-947-24	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/01/2021	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	8
Part 2	1 BLISTER PACK	16

Part 1 of 2

NIGHT COLD AND FLU RELIEF

acetaminophen, capsule, liquid filled

Product Information	
Item Code (Source)	NDC:11673-946
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	72
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-946-08	8 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	07/01/2021	

Part 2 of 2

DAY COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Item Code (Source)	NDC:11673-945
Route of Administration	ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SHELLAC (UNII: 46N107B71O)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	70
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-945-16	16 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	07/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2021	

Labeler - TARGET CORP (006961700)

Registrant - TIME CAP LABS INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11673-947)

Revised: 12/2020

TARGET CORP