COLD AND FLU DAYTIME-NIGHTTIME- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl
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 COLD AND FLU DAYTIME-NIGHTTIME SEVERE 11673-984

COLD AND FLU DAYTIME SEVERE SOFTGELS (625T)
DRUG FACTS

Active ingredients (in each softgel)
ACETAMINOPHEN 325MG
D0EXTROMETHORHAN HBR10 MG,
GUAIFENESIN 200 MG
, PHENYLEPHRINE HCL 5 MG

- 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.

Warnings
Liver warning - This product contains acetaminophen. Severe liver damage may occur if you take - more than 8sogtgels
This product contains acetaminophen.
Severe liver damage may occur if you take
more than 8 LiquiCaps 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.

FD&C Blue No.1,FD&C Red No. 40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac,sorbitol sorbitan solution, titanium dioxide

Directions
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

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.

PAIN RELIEVER-FEVER REDUCER

COUGH SUPPRESENT

MINOR ACHES AND PAINS

CHEST CONGESTION

COLD AND FLU NIGHTIME SEVERE SOFTGELS (626T)
DRUG FACTS

3 (in each softgel)
Acetaminophen 325mg
Dextromethorphan HBR 10 mg
Doxylamine Succinate 6.25 mg
PhenylephrineHCl,

Purpose

- Pain reliever/Fever reducer
- Cough suppressant
- Antihistamine
- Nasal decongestant

MINOR ACHES AND PAINS, FEVER

NASAL CONGESTION AND SINUS PRESSURE

SNEEZING, RUNNY NOSE

COUGH

Minor Aches & Pains
Nasal/Sinus Congestion
& Sinus Pressure
Sneezing, Runny Nose
Cough

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 ...

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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.

Directions
take only as directed - do not exceed 8 softgels 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

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

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Keep out of reach of children.
Overdose warning
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

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COLD AND FLU DAYTIME-NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11673-984

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-984-24	24 in 1 CARTON	06/03/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

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

Part 1 of 2

COLD AND FLU DAYTIME SEVERE

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

Product Information	
Item Code (Source)	NDC:11673-972
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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
POVIDONE (UNII: FZ989GH94E)	

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		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	06/03/2020	

Part 2 of 2

COLD AND FLU NIGHTTIME SEVERE

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled

Product Information	
Item Code (Source)	NDC:11673-983
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 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**
GELATIN (UNII: 2G86QN327L)	
SHELLAC (UNII: 46N107B71O)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	green	**Score**	no score
Shape	BULLET	**Size**	16mm
Flavor		**Imprint Code**	72
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		4 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	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/03/2020	

Labeler - TARGET CORP (006961700)

Registrant - TIME CAP LABS INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11673-984)

Revised: 5/2020 TARGET CORP