

**MAXIMUM STRENGTH DAYTIME - NIGHTTIME COLD AND FLU COLD AND FLU-  
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, doxylamine succinate  
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 MAX STRENGTH COLD AND FLU DAYTIME-NIGHTTIME 11673-925**

**MAXIMUM STRENGTH DAYTIME COLD AND FLU  
DRUG FACTS**

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

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- temporarily relieves common cold/flu symptoms: nasal congestion, headache, cough, minor aches and pains, sore throat
  - temporarily reduces fever
  - 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
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**Warnings**

**Liver warning** - This product contains acetaminophen. Severe liver damage may occur if you take - more than 8 softgels

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.

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FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

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**Do not take more than directed (See Overdose warning section) - do not exceed 12 Softgels per 24**

hr period

- adults & children 12 yrs & over 2 Softgels every 4 hrs
  - children 4 to under 12 yrs: Do not use
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Keep out of reach of children.

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. 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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PAIN RELIEVER-FEVER REDUCER

COUGH SUPPRESSANT

MINOR ACHES AND PAINS

CHEST CONGESTION

### Maximum Strength Nighttime Cold and Flu Drug Facts

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(in each softgel)

Acetaminophen 325mg

Dextromethorphan HBR 10 mg

Doxylamine Succinate 6.25 mg

PhenylephrineHCl 5mg

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Purpose

- Pain reliever/Fever reducer
  - Cough suppressant
  - Antihistamine
  - Nasal decongestant
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MINOR ACHES AND PAINS, FEVER

NASAL CONGESTION AND SINUS PRESSURE

SNEEZING, RUNNY NOSE

COUGH

PAIN RELIEVER-FEVER REDUCER

COUGH SUPPRESSANT

MINOR ACHES AND PAINS

NASAL DECONGESTION

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.

**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

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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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<p>Compare to active ingredients in Maximum Strength Mucinex<sup>®</sup> Fast-Max<sup>®</sup> Day Cold &amp; Flu<sup>®</sup></p> <p><b>maximum strength daytime cold and flu acetaminophen</b>  <small>(pain reliever/fever reducer)</small>  <small>(cough suppressant)</small>  <small>(antihistamine)</small>  <small>(nasal decongestant)</small></p> <p>relieves aches, fever, and sore throat  controls cough  relieves nasal congestion  relieves runny nose and sneezing  relieves mucus</p> <p>fast dissolving softgels</p>  <p>ACTUAL SIZE AGES 12+ YEARS</p> <p>16 SOFTGELS (100 mg/325 mg) 24 TOTAL SOFTGELS</p>	<p>NDC 11673-925-24</p> <p>Compare to active ingredients in Maximum Strength Mucinex<sup>®</sup> Fast-Max<sup>®</sup> Night Cold &amp; Flu<sup>®</sup></p> <p><b>maximum strength nighttime cold and flu acetaminophen</b>  <small>(pain reliever/fever reducer)</small>  <small>(cough suppressant)</small>  <small>(antihistamine)</small>  <small>(nasal decongestant)</small></p> <p>relieves aches, fever and sore throat  controls cough  relieves nasal congestion  relieves runny nose and sneezing</p> <p>fast dissolving softgels</p>  <p>ACTUAL SIZE AGES 12+ YEARS</p> <p>8 SOFTGELS (100 mg/325 mg)</p>
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**MAXIMUM STRENGTH DAYTIME - NIGHTTIME COLD AND FLU COLD AND**

# FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, doxylamine succinate kit

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-925
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-925-24	24 in 1 CARTON	07/07/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Quantity of Parts

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

## Part 1 of 2

### MAXIMUM STRENGTH COLD AND FLU

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

## Product Information

Item Code (Source)	NDC:11673-978
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Route of Administration	ORAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 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 YELLOW NO. 6 (UNII: H77VEI93A8)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KO0R)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

GLYCERIN (UNII: PDC6A3C0OX)

SORBITOL (UNII: 506T60A25R)

### Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	10 mm
Flavor		Imprint Code	78
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	07/07/2020	

## Part 2 of 2

### MAXIMUM STRENGTH NIGHTTIME COLD AND FLU

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

### Product Information

Item Code (Source)	NDC:11673-979
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
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

### Inactive Ingredients

Ingredient Name	Strength
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GLYCERIN (UNII: PDC6A3C00X)	
GELATIN (UNII: 2G86QN327L)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
WATER (UNII: 059QF0K00R)	
POVIDONE (UNII: FZ989GH94E)	

**Product Characteristics**

Color	green	Score	no score
Shape	CAPSULE	Size	24mm
Flavor		Imprint Code	72
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	07/07/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/07/2020	

**Labeler** - TARGET CORP (006961700)

**Registrant** - TIME CAP LABS INC (037052099)

**Establishment**

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11673-925)