DAYTIME AND NIGHTTIME SEVERE HONEY COLD AND FLU- daytime - acetaminophen, dextromethorphan hbr, guaifenesin and nighttime - acetaminophen, dextromethorphan hbr, doxylamine succinate TARGET CORPORATION

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# 745L Target Daytime Severe Honey and Nighttime Severe Honey Cold & Flu Combo Pack (Without PE)

Nighttime Severe Honey Cold & Flu

#### **Drug Facts**

## Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

## **Purpose**

Pain reliever/fever reducer Cough suppressant

**Antihistamine** 

Nasal decongestant

#### Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

## Warnings

#### Liver warning:

This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4 doses (30 mL each) in 24 hours, which is the maximum daily amount for this product
- child takes more than 4 doses (15 mL each) in 24 hours, which is the maximum daily amount for this product
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks daily 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 is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- to make a child sleepy

## Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- · trouble urinating due to enlarged prostate gland

## Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

# When using this product

- · do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

## Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or lasts more than 5 days (children) 7 days (adults)
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with rash or headache that lasts.

These could be signs of a serious condition.

## If pregnant or breast-feeding,

ask a health professional before use.

## 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.

#### **Directions**

- take only as directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children
12 yrs & over
children 6 to under
12 yrs
children 4 to under do not use unless
6 yrs
children under 4
yrs

30 mL every 4 hrs
15 mL every 4 hrs
do not use unless
directed by a doctor
do not use

#### Other information

- each 15 mL contains: sodium 14 mg
- Store at no greater than 25°C and do not refrigerate.

citric acid, D&C Yellow No. 10, FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 6, flavor, glycerin, propylene glycol, saccharin sodium, sodium benzoate, sodium citrate,

#### **Questions?**

1-877-290-4008

Daytime Severe Honey Cold & Flu

#### **Drug Facts**

## Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

## **Purpose**

Pain reliever/fever reducer Cough suppressant

Expectorant

Nasal decongestant

#### 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 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

• adult takes more than 4 doses (30 mL each) in 24 hours, which is the maximum daily

- amount for this product
- child takes more than 4 doses (15 mL each) in 24 hours, which is the maximum daily amount for this product
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks daily 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 is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

## Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

## Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product, do not use more than directed

# Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or lasts more than 5 days (children) 7

days (adults)

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with rash or headache that lasts.

These could be signs of a serious condition.

#### If pregnant or breast-feeding,

ask a health professional before use.

#### 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.

#### **Directions**

- · take only as directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & 30 mL every 4 over hrs

children 6 to under 12 yrs

children 4 to under 6 yrs ask a doctor children under 4 yrs

30 mL every 4 hrs

15 mL every 4 hrs

children 4 to under 6 yrs ask a doctor do not use

#### Other information

- each 15 mL contains: sodium 14 mg
- Store at no greater than 25°C and do not refrigerate

# Inactive ingredients

citric acid, D&C Yellow No. 10, FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 6, flavor, glycerin, propylene glycol, saccharin sodium, sodium benzoate, sodium citrate, sorbitol, sucralose, water, xanthan gum

## **Questions?**

1-877-290-4008



#### DAYTIME AND NIGHTTIME SEVERE HONEY COLD AND FLU

daytime - acetaminophen, dextromethorphan hbr, guaifenesin and nighttime - acetaminophen, dextromethorphan hbr, doxylamine succinate kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11673-791

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:11673-791- 02	1 in 1 CARTON; Type 0: Not a Combination Product	05/01/2024			

Quant	Quantity of Parts		
Part # Package Quantity		Total Product Quantity	
Part 1	1 BOTTLE	354 mL	
Part 2	1 BOTTLE	354 mL	

# Part 1 of 2

# **DAYTIME SEVERE HONEY COLD AND FLU**

acetaminophen, dextromethorphan hbr, guaifenesin liquid

#### **Product Information**

Item Code (Source) NDC:11673-796

**Route of Administration** ORAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL			
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL			
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL			

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
XANTHAN GUM (UNII: TTV12P4NEE)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
GLYCERIN (UNII: PDC6A3C0OX)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			

Product Characteristics			
Color brown Score			
Shape		Size	
Flavor	HONEY	Imprint Code	
Contains			

Packaging				
# Item Package Description		Marketing Start Date	Marketing End Date	
1		354 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing In			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/01/2024	

# Part 2 of 2

# **NIGHTTIME SEVERE HONEY COLD AND FLU**

acetaminophen, dextromethrophan, doxylamine succinate liquid

<b>Product Information</b>	
Item Code (Source)	NDC:11673-797
Route of Administration	ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL		

Inactive Ingredients			
Ingredient Name	Strength		
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SORBITOL (UNII: 506T60A25R)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
XANTHAN GUM (UNII: TTV12P4NEE)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			

SODIUM CITRATE (UNII: 1Q73Q2JULR)

FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)

Product Characteristics			
Color brown Score			
Shape		Size	
Flavor	HONEY	Imprint Code	
Contains			

Packaging					
	# Item Package Description		Marketing Start Date	Marketing End Date	
	1		354 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	05/01/2024			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M012	05/01/2024				

# Labeler - TARGET CORPORATION (006961700)

# **Registrant -** TIME CAP LABORATORIES, INC. (037052099)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
MARKSANS PHARMA LIMITED		677604129	manufacture(11673-791)				

Revised: 12/2023 TARGET CORPORATION