#### DAYTIME SEVERE COLD AND COUGH AND NIGHTTIME SEVERE COLD AND COUGHacetaminophen, dextromethorphan hbr, diphenhydramine hcl, phenylephrine hcl Target Corporation

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.

## daytime severe cold and cough & nighttime severe cold and cough value pack

# Active ingredients (in each packet) – Daytime Severe Cold and Cough

Acetaminophen 650 mg Dextromethorphan HBr 20 mg Phenylephrine HCl 10 mg

## Active ingredients (in each packet) - Nighttime Severe Cold and Cough

Acetaminophen 650 mg Diphenhydramine HCl 25 mg Phenylephrine HCl 10 mg

## Purposes - Daytime Severe Cold and Cough

Pain reliever/fever reducer Cough Suppressant Nasal Decongestant

# Purpose - Nighttime Severe Cold and Cough

Pain reliever/fever reducer Antihistamine/cough Suppressant Nasal Decongestant

# Uses - Daytime Severe Cold and Cough

- temporarily relieves these symptoms due to a cold:
- minor aches and pains
- minor sore throat pain
- headache
- nasal and sinus congestion
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

## Uses - Nighttime Severe Cold and Cough

• temporarily relieves these symptoms due to a cold:

- minor aches and pains
- minor sore throat pain
- headache
- nasal and sinus congestion
- runny nose
- sneezing
- itchy nose or throat
- itchy, watery eyes due to hay fever
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

## Warnings – Daytime Severe Cold and Cough and Nighttime Severe Cold and Cough

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 reactions. Symptoms may include:

•Skin reddening • blisters • rash

Is 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.

## Do not use - Daytime Severe Cold and Cough

- in a child under 12 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a 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.

# Do not use - Nighttime Severe Cold and Cough

- in a child under 12 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- 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 a MAOI, ask a doctor or pharmacist before taking this product.

# Ask a doctor before use if you have - Daytime Severe Cold and Cough

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

# Ask a doctor before use if you have - Nighttime Severe Cold and Cough

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

# Ask a doctor or pharmacist before use if you are - Daytime Severe Cold and Cough

taking the blood thinning drug warfarin

# Ask a doctor or pharmacist before use if you are - Nighttime Severe Cold and Cough

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

# When using this product - Daytime Severe Cold and Cough

do not exceed recommended dosage

# When using this product - Nighttime Severe Cold and Cough

- do not exceed recommended dosage
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

# Stop use and ask a doctor if – Daytime Severe Cold and Cough /Nighttime Severe Cold and Cough

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- 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 (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Directions – Daytime Severe Cold and Cough

#### • do not use more than directed

• take every 4 hours, while symptoms persist, Do not take more than 5 packets in 24 hours unless directed by a doctor

Age	Dose
Adults and children 12 years of age and over	One packet
Children under 12 years of age	Do not use

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat

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# Other information - Daytime Severe Cold and Cough

- each packet contains: potassium 6 mg
- store at room temperature. Protect from excessive heat and moisture

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## Inactive ingredients - Daytime Severe Cold and Cough

citric acid ,FD&C blue#1, FD&C red 40#, flavors, maltodextrin, potassium chloride, silica, sucralose, sucrose

## Inactive ingredients - Nighttime Severe Cold and Cough

citric acid, FD & C yellow #6, flavors, maltodextrin, potassium chloride, silica, sucralose, sucrose,

## Questions or comments?

1-866-467-2748

## Package/Label Principal Display Panel

Compare to active ingredients in Theraflu® Daytime Severe Cold and Cough and Nighttime Severe Cold & Cough\*

Value pack

## daytime severe cold and cough

acetaminophen(pain reliever/ fever reducer) dextromethorphan HBr ( cough suppressant) phenylephrine HCl ( nasal decongestant) aspartame free, sodium free relief of nasal and sinus congestion,, cough ,body ache, sore throat pain, headache ,fever berry flavor infused with menthol and green tea flavors 6 PACKETS **nighttime severe cold and cough** acetaminophen –(pain reliever/ fever reducer) diphenhydramine HCl – (antihistamine/ cough suppressant) phenylephrine HCl – (nasal decongestant)

aspartame free, sodium free

relief of nasal congestion,, cough ,runny nose, sneezing, body ache, sore throat pain, headache ,fever

honey lemon flavor infused with chamomile & white tea flavors

6 PACKETS

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE .KEEP CARTON FOR REFERENCE, DO NOT DISCARD.

DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME OR TAKE MORE THAN 5 DOSES IN TOTAL IN ANY 24 –HOUR PERIOD.

## DO NOT TAKE A DOSE OF THE NIGHTTIME PRODUCT SOONER THAN 4 HOURS AFTER THE LAST DOSE OF DAYTIME PRODUCT UNLESS DIRECTED BY DOCTOR.

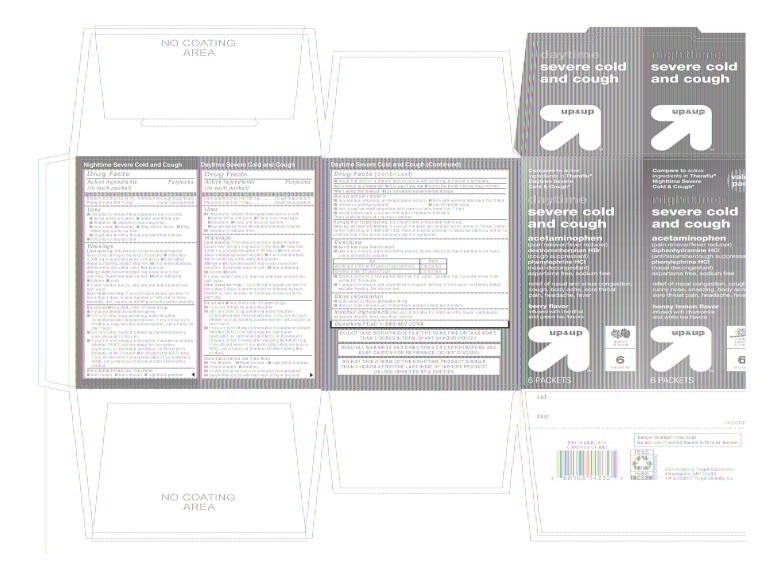
\*These Products are not manufactured or distributed by GSK Consumer Healthcare, distributor of Theraflu Daytime Severe Cold & Cough and Theraflu Nighttime severe Cold & Cough

Distributed by: Target Corporation.

Minneapolis, MN 55403

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Tamper Evident Inner Unit Do not use if sealed packet is Torn or Broken



# DAYTIME SEVERE COLD AND COUGH AND NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, dextromethorphan hbr, diphenhydramine hcl, phenylephrine hcl kit

Product Informa	ation				
Product T ype	HUMAN OTC DRUG	Item Code	(Source)	NDC:11673-542	
Packaging					
# Item Code	Package Descrip	tion	Marketing Start Date	Marketing End Date	
1 NDC:11673-542-12	1 in 1 CARTON; Type 0: Not a Com	1 in 1 CARTON; Type 0: Not a Combination Product 07/31/2017			
Quantity of Part	s				
Part #	Package Quantity		Total Product Qu	antity	
Part 1 1 CARTON		6			
Part 2 1 CARTON		6			

## Part 1 of 2

# DAYTIME SEVERE COLD AND COUGH

acetaminophen, dextromethorphan hbr, phenylephrine hcl powder, for solution

Product	Information

Item Code (Source)NDC:11673-540Route of AdministrationORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

#### **Inactive Ingredients**

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Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CHLORIDE (UNII: 660 YQ98110)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8 M554)	

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-540-06	6 in 1 CARTON; 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	07/31/2017	

# Part 2 of 2

# NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine hcl, phenylephrine hcl powder, for solution

<b>Product Informa</b>	tion					
Item Code (Source)		NDC:11673-541				
Route of Administra	tion	ORAL				
Active Ingredien	t/Active Moi	ety				
	Ingr	edient Name		Basis of St	rength	Strength
ACETAMINOPHEN (U	NII: 36209ITL9I	) (ACETAMINOPHEN - UNII:362O9ITLS	)D)	ACETAMINOPHEN		650 mg
<b>DIPHENHYDRAMINE</b> UNII:8GTS82S83M)	HYDROCHLOR	IDE (UNII: TC2D6JAD40) (DIPHENHYDF	AMINE -	DIPHENHYDRAMIN HYDROCHLORIDE	E	25 mg
PHENYLEPHRINE HY UNII:1WS297W6MV)	DRO CHLO RIDE	E (UNII: 04JA59TNSJ) (PHENYLEPHRINE	-	PHENYLEPHRINE HYDROCHLORIDE		10 mg
Inactive Ingredie	nts					
		Ingredient Name			Stre	ength
ANHYDRO US CITRIC	ACID (UNII: XF4	417D3PSL)				
MALTO DEXTRIN (UN	NII: 7CVR7L4A2D	)				
POTASSIUM CHLOR	<b>IDE</b> (UNII: 660 Y	298110)				
SILICON DIO XIDE (U	NII: ETJ7Z6 XBU	4)				
SUCRALOSE (UNII: 9)	6K6UQ3ZD4)					
SUCROSE (UNII: C151	H8 M554)					
FD&C YELLOW NO.	<b>6</b> (UNII: H77VEI9	3A8)				
Packaging						
00	]	Package Description	Marke	ting Start Date	Marketing	g End Date
# Item Code		Package Description Type 0: Not a Combination Product	Market	ing Start Date	Marketing	g End Date
# Item Code			Market	ting Start Date	Marketing	g End Date
<ul> <li># Item Code</li> <li>1 NDC:11673-541-06</li> </ul>	6 in 1 CARTON		Marke	ing Start Date	Marketing	g End Date
<ul> <li># Item Code</li> <li>1 NDC:11673-541-06</li> <li>Marketing Inf</li> <li>Marketing Categor</li> </ul>	6 in 1 CARTON			ting Start Date eting Start Date		g End Date g End Date
1 NDC:11673-541-06 Marketing Inf	6 in 1 CARTON	Type 0: Not a Combination Product		eting Start Date		
<ul> <li># Item Code</li> <li>1 NDC:11673-541-06</li> <li>Marketing Inf</li> <li>Marketing Categor</li> <li>OTC monograph final</li> </ul>	6 in 1 CARTON Ormation y Applicatio part341	Type 0: Not a Combination Product	Mark	eting Start Date		
<ul> <li># Item Code</li> <li>1 NDC:11673-541-06</li> <li>Marketing Inf</li> <li>Marketing Categor</li> </ul>	6 in 1 CARTON ormation y Application part341 ormation	Type 0: Not a Combination Product	<b>Mark</b> 07/31/2	eting Start Date	Marketinş	

Marketing Category	Application Number or Monograph Citation	Marketing Start Date
OTC monograph final	part341	07/31/2017

Labeler - Target Corporation (006961700)