# SIGNATURE CARE SEVERE COLD COUGH AND FLU NIGHTTIME- acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution Safeway

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.

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## Better Living Brands LLC Severe Cold, Cough & Flu Drug Facts

## Active ingredients (in each packet)

Acetaminophen 650 mg
Diphenhydramine HCl 25 mg
Phenylephrine HCl 10 mg

#### **Purposes**

Pain reliever/fever reducer
Antihistamine/cough suppressant
Nasal decongestant

#### Uses

- 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**

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

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.

#### Do not use

- in a child under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or 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 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
- 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

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

# When using this product

- 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

- 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.

Overdose warning: 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**

- do not use more than directed (see overdose warning)
- 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.

#### Other information

- each packet contains: potassium 10 mg and sodium 25 mg
- phenylketonurics: contains phenylalanine 13 mg per packet
- store at 20-25°C (68-77°F). Protect product from heat and moisture.

# **Inactive ingredients**

acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, D&C yellow #10, FD&C blue #1, FD&C red #40, flavors, maltodextrin, pregelatinized starch,

#### **Questions or comments?**

1-888-723-3929

# Package/Label Principal Display Panel

COMPARE TO Theraflu® Nighttime Severe Cold & Cough active ingredients

Nighttime

Severe Cold, Cough & Flu

**ACETAMINOPHEN** 

Pain Reliever/Fever Reducer

DIPHENHYDRAMINE HCI

Antihistamine/Cough Suppressant

PHENYLEPHRINE HCI

**Nasal Decongestant** 

HONEY LEMON INFUSED WITH WHITE TEA FLAVORS

**Nasal Congestion** 

Cough

Runny Nose

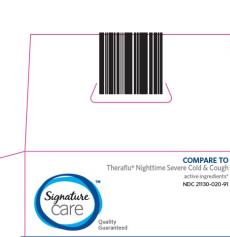
Sneezing

**Body Ache** 

Sore Throat Pain

Headache/Fever

6 PACKETS



**Nighttime** 

Severe

**ACETAMINOPHEN** 

PHENYLEPHRINE HCI Nasal Decongestant

DIPHENHYDRAMINE HCI

Cold, Cough & Flu

6 PACKETS







**Nighttime** 

Severe

Cold,

Cough & Flu

DISTRIBUTED BY BETTER LIVING BRANDS LLC P.O. BOX 99, PLEASANTON, CA 94566-0009 1-898-723-3929 www.betterlivingbrands.L.C.com

MADE IN MEXICO

GUARANTEED



#### Drug Facts

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Diphenhydramine HCl 25 mg Phenylephrine HCl 10 mg	Antihistamine/cough suppressant
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OPEN OTHER END



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#### Drug Facts (continued)

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#### Questions or comments? 1-888-723-3929

\*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Theraflu® Nighttime Severe Cold & Cough.



acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder, for solution

#### **Product Information**

**Product Type HUMAN OTC DRUG Item Code (Source)** NDC:21130-020

**Route of Administration** ORAL

#### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) **ACETAMINOPHEN** 650 mg **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6JAD40) DIPHENHYDRAMINE 25 mg (DIPHENHYDRAMINE - UNII:8GTS82S83M) **HYDROCHLORIDE PHENYLEPHRINE** PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -10 mg UNII:1WS297W6MV) **HYDROCHLORIDE**

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
ASPARTAME (UNII: Z0H242BBR1)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SUCROSE (UNII: C151H8M554)		
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)		

Product Characteristics			
Color	WHITE (mixture of white, light yellow-orange particles) , ORANGE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:21130-020- 91	6 in 1 CARTON; Type 0: Not a Combination Product	10/27/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/27/2015	

# **Labeler -** Safeway (009137209)

Revised: 11/2022 Safeway