

# **COLD AND FLU SEVERE DAYTIME- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride capsule, liquid filled**

**TOPCO ASSOCIATES LLC**

*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.*

-----

## **Cold and Flu Severe Daytime**

### **Drug Facts**

<b>Active ingredients (in each softgel)</b>	<b>Purposes</b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	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 you take:

- more than 8 softgels in 24 hours, 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.

## **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
- glaucoma
- trouble urinating due to enlarged prostate gland
- a sodium-restricted diet
- 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; taking sedatives or tranquilizers.

**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 7 days
- 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.**

### **Overdose warning**

In case of overdose, get medical help or contact a Poison Control Center right away.

### **Directions**

- take only as directed
- do not exceed 8 softgels per 24 hrs

adults & children 12 yrs & over	2 softgels with water every 4 hours
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

### **Other information**

- store at 20-25°C (68-77°F)
- protect from light, heat and moisture

### **Inactive ingredients**

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

### **Questions?**

Call toll free: **1-888-423-0139**

### **PRINCIPAL DISPLAY PANEL - 24 Softgel Blister Pack Carton**

NDC: 36800-826-24

\*Compare to the active ingredients  
in Vicks<sup>®</sup> Dayquil<sup>™</sup> Severe Cold & Flu

MULTI-SYMPTOM RELIEF

Day Time  
Cold & Flu Relief  
SEVERE

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN  
COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr  
EXPECTORANT - GUAIFENESIN  
NASAL DECONGESTANT - PHENYLEPHRINE HCl

- Headache, Fever, Sore Throat, Minor Aches & Pains

- Sinus Congestion & Pressure
- Nasal Congestion • Cough

Alcohol Free  
Antihistamine Free  
Non-Drowsy

24 SOFTGELS

actual size



LOT: EXP:

NDC: 36800-826-24

\*Compare to the active ingredients in Vicks® Dayquil™ Severe Cold & Flu

**Drug Facts**  
 Active ingredients (in each softgel)  
 Acetaminophen 325 mg  
 Dextromethorphan Hbr 10 mg  
 Guaifenesin 200 mg  
 Phenylephrine HCl 5 mg  
 Nasal decongestant  
 Expectorant  
 Cough suppressant  
 Pain reliever/fever reducer

**Purposes**

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

MULTI-SYMPOM RELIEF

# Day Time

## Cold & Flu Relief

### SEVERE

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN  
 COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr  
 EXPECTORANT - GUAIFENESIN  
 NASAL DECONGESTANT - PHENYLEPHRINE HCl

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sinus Congestion & Pressure
- Nasal Congestion • Cough

Alcohol Free  
 Antihistamine Free  
 Non-Drowsy



actual size

## 24 SOFTGELS

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT

**Drug Facts (continued)**  
 Other information ■ store at 20-25°C (68-77°F) ■ protect from light, heat and moisture  
 Inactive ingredients ■ FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide  
 Questions? Call toll free: 1-888-423-0139

▲ This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® Dayquil™ Severe  
 CT3680082624

**Drug Facts (continued)**

**Uses**  
 temporarily relieves common cold/flu symptoms:  
 ■ nasal congestion ■ sinus congestion & pressure  
 ■ cough due to minor throat & bronchial irritation ■ fever ■ sore throat  
 ■ minor aches & pains ■ headache  
 ■ 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 8 softgels in 24 hours, 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.  
 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.

**Directions**  
 ■ Take only as directed  
 ■ do not exceed 8 softgels per 24 hrs  
 adults & children 12 yrs & over ■ 2 softgels with water every 4 hours  
 children 4 to under 12 yrs ■ ask a doctor  
 children under 4 yrs ■ do not use

**Warnings (continued)**  
 ■ you get nervous, dizzy or sleepless  
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days  
 ■ 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.  
 Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions (continued)**  
 Control Center right away.

**Warnings (continued)**  
 ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ glaucoma ■ trouble urinating due to enlarged prostate gland ■ a sodium-restricted diet ■ 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; taking sedatives or tranquilizers.**

**When using this product, do not use more than directed.**

**Stop use and ask a doctor if**



## COLD AND FLU SEVERE DAYTIME

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-986
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C Yellow no. 6</b> (UNII: H77VEI93A8)	
<b>Gelatin, unspecified</b> (UNII: 2G86QN327L)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Polyethylene Glycol, unspecified</b> (UNII: 3WJQ0SDW1A)	
<b>Povidone K30</b> (UNII: U725QWY32X)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	782
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-986-24	2 in 1 CARTON	05/01/2021	

1	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part341	05/01/2021	

**Labeler** - TOPCO ASSOCIATES LLC (006935977)

Revised: 1/2023

TOPCO ASSOCIATES LLC