

**COLD AND FLU SEVERE DAYTIME/NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate, and phenylephrine hydrochloride**  
**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.*

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**Cold and Flu Severe Daytime/Nighttime**

**DAYTIME SEVERE COLD AND FLU RELIEF**

**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
- a sodium-restricted diet
- 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; 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 and over	2 softgels with water every 4 hrs
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?**

**1-888-423-0139**

### **NIGHTTIME SEVERE COLD AND FLU RELIEF**

### ***Drug Facts***

<b><i>Active ingredients (in each softgel)</i></b>	<b><i>Purposes</i></b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
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
- 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 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
- a sodium-restricted diet
- trouble urinating due to enlarged prostate gland
- 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

**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 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 hours

adults & children 12 yrs and over	2 softgels with water every 4 hrs
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**

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone K30, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

### **Questions?**

**1-888-423-0139**

### **PRINCIPAL DISPLAY PANEL - Kit Carton**

NDC 36800-829-24

\*Compare to the active ingredients  
in Vicks<sup>®</sup> DayQuil<sup>™</sup> Severe

MULTI-SYMPTOM RELIEF

DayTime

Cold & Flu Relief  
SEVERE

Acetaminophen - Pain reliever/Fever reducer  
Dextromethorphan HBr - Cough suppressant  
Guaifenesin - Expectorant  
Phenylephrine HCl - Nasal decongestant

Non-drowsy  
Alcohol free  
Antihistamine free

actual size

12 SOFTGELS

\*Compare to the active ingredients  
in Vicks<sup>®</sup> NyQuil<sup>™</sup> Severe

MULTI-SYMPTOM RELIEF

NightTime

Cold & Flu Relief  
SEVERE

Acetaminophen - Pain reliever/Fever reducer  
Dextromethorphan HBr - Cough suppressant  
Doxylamine succinate - Antihistamine  
Phenylephrine HCl - Nasal decongestant

actual size

12 SOFTGELS

TOTAL 24  
SOFTGELS

**Drug Facts (continued)**

**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 ■ a sodium-restricted diet

**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
- you get pain, nasal congestion, or cough gets worse or lasts more than 7 days

**DAYTIME SEVERE COLD AND FLU RELIEF**

**Drug Facts (continued)**

**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 ■ a sodium-restricted diet

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers

**When using this product**

- do not use more than directed
- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur

**NIGHTTIME SEVERE COLD AND FLU RELIEF**

**Drug Facts**

**Active ingredients (in each softgel)**

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
- temporarily restores free breathing through the nose
- reduces swelling of nasal passages
- minor aches & pains ■ fever ■ sore throat
- temporarily restores free breathing through the nose
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages or 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

3 or more other drugs containing acetaminophen

with other drugs containing acetaminophen

more than 8 softgels in 24 hours, which is the maximum daily amount for this product

if skin reaction occurs, stop use and seek medical help right away.

Symptoms may include: ■ skin redness ■ hives ■ rash

Allergy alert: Acetaminophen may cause severe skin reactions.

**DAYTIME SEVERE COLD AND FLU RELIEF**

**Drug Facts**

**Active ingredients (in each softgel)**

Acetaminophen 325 mg.....Pain reliever/fever reducer  
 Dextromethorphan HBr 10 mg.....Cough suppressant  
 Doxylamine succinate 6.25 mg.....Antihistamine  
 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
- temporarily restores free breathing through the nose
- reduces swelling of nasal passages
- runny nose & sneezing
- minor aches & pains ■ fever ■ sore throat
- temporarily restores free breathing through the nose
- promotes nasal and/or sinus drainage

**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

3 or more other drugs containing acetaminophen

with other drugs containing acetaminophen

more than 8 softgels in 24 hours, which is the maximum daily amount for this product

if skin reaction occurs, stop use and seek medical help right away.

Symptoms may include: ■ skin redness ■ hives ■ rash

Allergy alert: Acetaminophen may cause severe skin reactions.

**NIGHTTIME SEVERE COLD AND FLU RELIEF**

**DO NOT TAKE THESE PRODUCTS AT THE SAME TIME**

**MULTI-SYMPTOM RELIEF**

# Daytime

## Cold & Flu Relief SEVERE

NDC 36800-829-24 \*Compare to the active ingredients in Vicks® DayQuil™ Severe

**MULTI-SYMPTOM RELIEF**

# Night Time

## Cold & Flu Relief SEVERE

\*Compare to the active ingredients in Vicks® NyQuil™ Severe

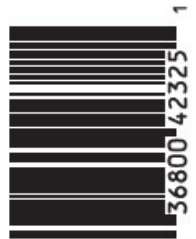
**MULTI-SYMPTOM RELIEF**

# DayTime

**MULTI-SYMPTOM RELIEF**

# NightTime

THIS PRODUCT IS TAMPER EVIDENT PAC





PACKAGED IN A CHILD RESISTANT AND KAGE. USE ONLY IF BLISTERS ARE INTACT.

## Cold & Flu Relief SEVERE

*Acetaminophen* - Pain reliever/Fever reducer  
*Dextromethorphan HBr* - Cough suppressant  
*Guaifenesin* - Expectorant  
*Phenylephrine HCl* - Nasal decongestant

Non-drowsy  
 Alcohol free  
 Antihistamine free



actual size

**12 SOFTGELS**

## Cold & Flu Relief SEVERE

*Acetaminophen* - Pain reliever/Fever reducer  
*Dextromethorphan HBr* - Cough suppressant  
*Doxylamine succinate* - Antihistamine  
*Phenylephrine HCl* - Nasal decongestant



actual size

**12 SOFTGELS**

**TOTAL 24 SOFTGELS**

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

LOT:  
 EXP:

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\*These products are not manufactured or distributed by Procter & Gamble, owner of the registered trademarks Vicks® DayQuil™ & NyQuil™ Severe  
 REV-00-122020 CT3680082924

**DRUG FACTS (continued)**  
**INACTIVE INGREDIENTS**  
 D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone K30, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide  
**QUESTIONS?** 1-888-423-0139

**DAYTIME SEVERE COLD AND FLU RELIEF**  
**DRUG FACTS (continued)**  
 ■ 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 and over 2 softgels with water every 4 hrs  
 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?** 1-888-423-0139

**NIGHTTIME SEVERE COLD AND FLU RELIEF**  
**DRUG FACTS (continued)**  
 ■ 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 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 hours  
 adults & children 12 yrs and over 2 softgels with water every 4 hrs  
 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

## COLD AND FLU SEVERE DAYTIME/NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate, and phenylephrine hydrochloride kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-746
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-746-12	2 in 1 CARTON	05/01/2021	

1

1 in 1 BLISTER PACK

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1		8
Part 2		4

**Part 1 of 2****COLD AND FLU SEVERE DAYTIME**

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

**Product Information**

**Route of Administration** 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, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<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>			

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/01/2021	

## Part 2 of 2

### COLD AND FLU SEVERE NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride capsule, liquid filled

## Product Information

Route of Administration ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	789

**Contains****Marketing Information**

<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	

**Marketing Information**

<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: 3/2021

TOPCO ASSOCIATES LLC