

**TOPCARE DAY TIME NITE TIME COLD AND FLU- acetaminophen,  
dextromethorphan hbr, doxylamine succinate, phenylephrine hcl  
Topco Associates LLC**

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**Topco Associates LLC. Cold & Flu Severe Drug Facts**

**Nighttime Severe Cold & Flu  
Active ingredients (in each 30 mL)**

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine succinate 12.5 mg

Phenylephrine HCl 10 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

**Uses**

temporarily relieves common cold/flu symptoms:

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

**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**

- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

### **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 such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

### **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 (1-800-222-1222). 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 - see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

**Other information**

- **each 30 mL contains:** sodium 41 mg
- store at 20-25°C (68-77°F)

**Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

**Questions or comments?**

**1-888-423-0139**

## **Daytime Severe Cold & Flu**

### **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 and pressure
- cough due to minor throat and bronchial irritation
- minor aches and 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 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

### **Ask a doctor before use if you have**

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an 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) or 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.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 - see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

**Other information**

- **each 15 mL contains:** sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients - Daytime**

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

**Questions or comments?**

**1-888-423-0139**

**Principal Display Panel - Daytime**

TopCare® health

COMPARE TO VICKS® DAYQUIL® SEVERE and VICKS® NYQUIL® SEVERE ACTIVE INGREDIENTS

Cold & Flu Severe

DAY & NIGHT COMBO PACK

TopCare® health

COMPARE TO VICKS® DAYQUIL® SEVERE ACTIVE INGREDIENTS

MAXIMUM STRENGTH RELIEF

DayTime Cold & Flu

SEVERE

PAIN RELIEVER – FEVER REDUCER - ACETAMINOPHEN

COUGH SUPPRESSANT – DEXTROMETHORPHAN HBr

EXPECTORANT – GUAIFENESIN

NASAL DECONGESTANT – PHENYLEPHRINE HCl

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

Alcohol Free

Antihistamine Free

Non-Drowsy

12 FL OZ (355 mL)

ORIGINAL FLAVOR

TopCare® health

COMPARE TO VICKS® NYQUIL® SEVERE ACTIVE INGREDIENTS

MAXIMUM STRENGTH RELIEF

NiteTime Cold & Flu

SEVERE

PAIN RELIEVER – FEVER REDUCER – ACETAMINOPHEN

COUGH SUPPRESSANT – DEXTROMETHORPHAN HBr

ANTIHISTAMINE – DOXYLAMINE SUCCINATE

NASAL DECONGESTANT – PHENYLEPHRINE HCl

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal/Sinus Congestion & Sinus Pressure
- Sneezing, Runny Nose
- Cough

Alcohol Free

MIXED BERRY FLAVOR

MAX STRENGTH RELIEF DAY OR NIGHT

2 BOTTLES – 1 DAYTIME/1 NITETIME 12 FL OZ (355 mL) EACH; TOTAL 24 FL OZ (1.5 pt)

(710 mL)



COMPARE TO VICKS® DAYQUIL® SEVERE and VICKS® NYQUIL® SEVERE ACTIVE INGREDIENTS\*

# Cold & Flu Severe

## DAY & NIGHT COMBO PACK



COMPARE TO VICKS® DAYQUIL® SEVERE and VICKS® NYQUIL® SEVERE ACTIVE INGREDIENTS\*

NDC 36800-597-02

# Cold & Flu Severe

## DAY & NIGHT COMBO PACK



COMPARE TO VICKS® DAYQUIL® SEVERE ACTIVE INGREDIENTS\*

MAXIMUM STRENGTH RELIEF

### DayTime Cold & Flu

**SEVERE**

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



COMPARE TO VICKS® NYQUIL® SEVERE ACTIVE INGREDIENTS\*

MAXIMUM STRENGTH RELIEF

### NiteTime Cold & Flu

**SEVERE**

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN  
COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr  
ANTIHISTAMINE - DOXYLAMINE SUCCINATE  
NASAL DECONGESTANT - PHENYLEPHRINE HCl

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

Alcohol Free  
Antihistamine Free  
Non-Drowsy

ORIGINAL FLAVOR

MAX STRENGTH RELIEF DAY OR NIGHT

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal/Sinus Congestion & Sinus Pressure
- Sneezing, Runny Nose
- Cough

Alcohol Free



MIXED BERRY FLAVOR

2 BOTTLES-1 DAYTIME/1 NITETIME 12 FL OZ (355 mL) EACH; TOTAL 24 FL OZ (1.5 pt) (710 mL)

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

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IL 60007  
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QUESTIONS?  
1-888-423-0139  
topcare@topco.com  
www.topcarebrand.com



Scan here for more information or call 1-888-423-0139



GLUTEN FREE



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

### PARENTS:

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

\*These products are not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® Severe and Vicks® NyQuil® Severe.



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**Nighttime Severe Cold & Flu**

Drug Facts	
Active ingredients (in each 30 mL)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal decongestant

**Uses** temporarily relieves common cold/flu symptoms:

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

**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**  
 ■ 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.  
 ■ if you have ever had an allergic reaction to this product or any of its ingredients.

**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 such as emphysema or chronic bronchitis  
 ■ trouble urinating due to an enlarged prostate gland  
 ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema  
 ■ a sodium-restricted diet

**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 (1-800-222-1222). 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 - see Overdose warning
- only use the dose cup provided ■ do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

**Other information**  
 ■ each 30 mL contains: sodium 41 mg  
 ■ store at 20-25°C (68-77°F)

**Inactive ingredients** anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavoc glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

**Questions or comments?** 1-888-423-0139

**Daytime Severe Cold & Flu**

Drug Facts	
Active ingredients (in each 15 mL)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guafenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses** temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and 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 4,000 mg of acetaminophen in 24 hours  
 ■ child takes more than 5 doses in 24 hours  
 ■ taken with other drugs containing acetaminophen  
 ■ adult has 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.  
 ■ if you have ever had an allergic reaction to this product or any of its ingredients.

**Ask a doctor before use if you have**  
 ■ liver disease ■ heart disease ■ thyroid disease  
 ■ diabetes ■ high blood pressure  
 ■ trouble urinating due to an 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) or 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. Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 - see Overdose warning
- only use the dose cup provided ■ do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

**Other information**  
 ■ each 15 mL contains: sodium 6 mg  
 ■ store at 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients** butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavoc glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

**Questions or comments?** 1-888-423-0139

**DAY & NIGHT COMBO PACK**



**DayTime Cold & Flu SEVERE**



**NiteTime Cold & Flu SEVERE**

**MAX STRENGTH RELIEF DAY OR NIGHT**



ORIGINAL FLAVOR

MIXED BERRY FLAVOR



## TOPCARE DAY TIME NITE TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-597
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-597-02	1 in 1 CARTON; Type 0: Not a Combination Product	06/28/2014	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	355 mL
Part 2	1 BOTTLE	355 mL

## Part 1 of 2

## TOPCARE NITE TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution

### Product Information

<b>Item Code (Source)</b>	NDC:36800-763
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<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	RED (clear, dark)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-763-40	355 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	06/09/2014	

## Part 2 of 2

### TOPCARE DAY TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

## Product Information

<b>Item Code (Source)</b>	NDC:36800-603
<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 in 15 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	ORANGE (clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT, MENTHOL	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-603-40	355 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	06/13/2014	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/28/2014	

**Labeler** - Topco Associates LLC (006935977)

Revised: 10/2025

Topco Associates LLC