

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

Topco Associates LLC. Day Time Nite Time Cold & Flu Drug Facts

**Nite Time 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

Day Time 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

SPECIAL VALUE! COMBINATION PACK

TopCare® health

COMPARE TO VICKS® DAYQUIL® SEVERE ACTIVE INGREDIENTS

MAXIMUM STRENGTH RELIEF

Day Time 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

Nite Time 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

12 FL OZ (355 mL)

MIXED BERRY FLAVOR

SPECIAL VALUE! COMBINATION PACK



NDC:36800-597-02

COMPARE TO VICKS® DAYQUIL® SEVERE ACTIVE INGREDIENTS*

MAXIMUM STRENGTH RELIEF

Day Time 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



NDC:36800-597-02

COMPARE TO VICKS® NYQUIL® SEVERE ACTIVE INGREDIENTS*

MAXIMUM STRENGTH RELIEF

Nite Time Cold & Flu

SEVERE

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

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



12 FL OZ (355 mL)

MIXED BERRY FLAVOR



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

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 TOPCO ASSOCIATES LLC
 ELK GROVE VILLAGE, IL 60007
 ©TOPCO PERA0622
 QUESTIONS? 1-888-423-0139
 topcare@topco.com
 www.topcarebrand.com

Drug Facts (continued)

Inactive ingredients: airtinous 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

PARENTS:

Learn about teen medicine abuse
www.StopMedicineAbuse.org



DO NOT USE IF PRINTED NECK AND IS BROKEN OR MISSING

*These products are not manufactured or distributed by Pfizer & family, distributor of Vicks DayQuil Severe and Vicks Nyquil Severe.

Drug Facts (continued)

Inactive ingredients: buffered hydroxyacetate, 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

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TOPCARE DAY TIME NITE TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-597	
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

Item Code (Source)	NDC:36800-763
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED (clear, dark)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

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 final	part341	06/09/2014	

Part 2 of 2

TOPCARE DAY TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information

Item Code (Source)	NDC:36800-603
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	

SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	FRUIT, MENTHOL	Imprint Code	
Contains			

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 final	part341	06/13/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/28/2014	

Labeler - Topco Associates LLC (006935977)

Revised: 6/2023 Topco Associates LLC