

CVS OVERNIGHT COLD AND FLU CLEAR AND COOL- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution
CVS PHARMACY, INC

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.

CVS Nightshift Cold & Flu Clear & Cool

Drug Facts

Active ingredients (in Purposes each 20 mL)

Acetaminophen 650 mg Pain reliever/fever reducer

Dextromethorphan HBr 20 mg Cough suppressant

Phenylephrine HCl 10 mg Nasal decongestant

Triprolidine HCl 2.5 mg Antihistamine

Uses

- temporarily relieves these common cold and flu symptoms:
 - cough
 - nasal congestion
 - minor aches and pains
 - sore throat
 - headache
 - runny nose
 - sneezing
 - sinus congestion and pressure
 - itching of the nose or throat
 - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4000 mg in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

- 3 or more alcoholic drinks daily 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
- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

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**
- excitability may occur, especially in children
 - marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness

- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal decongestion, 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 fever, 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

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- **adults and children 12 years of age and over:** 20 mL in dosing cup provided every 4 hours
- **children under 12 years of age:** do not use

Other information

- **each 20 mL contains:** sodium 10 mg
- store at room temperature
- do not refrigerate

Inactive ingredients

anhydrous citric acid, ascorbic acid, D&C Yellow No. 10, edetate disodium, FD&C Blue No. 1, flavors, glycerin, propyl gallate, propylene glycol, sodium benzoate, sodium citrate, sorbitol, sucralose and xanthan gum

Questions?

1-866-467-2748

PRINCIPAL DISPLAY PANEL - 180 mL Bottle Label

NDC 69842-966-06

Nighttime Cold & Flu Clear & Cool

Acetaminophen - Pain Reliever/Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Phenylephrine HCl - Nasal Decongestant

Triprolidine HCl - Antihistamine

MULTI-SYMPTOM

- Controls Cough
- Relieves fever & sore throat
- Relieves Runny Nose & Sneezing
- Nasal decongestant

6 FL OZ (180 mL)

FOR AGES 12+

Tamper evident: do not use if printed seal under cap is broken or missing.

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS.com® 1-800-SHOP CVS V-12431

CVS® Quality

Money Back Guarantee

*This product is not manufactured or distributed by RB Health, the distributor of Mucinex® Nightshift Cold & Flu Clear & Cool.

CVS OVERNIGHT COLD AND FLU CLEAR AND COOL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69842-966 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|--------------------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg in 20 mL |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg in 20 mL |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg in 20 mL |
| TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM) | TRIPROLIDINE HYDROCHLORIDE | 2.5 mg in 20 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PROPYL GALLATE (UNII: 8D4SNN7V92) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|--|
| Color | GREEN | Score | |
| Shape | | Size | |
| Flavor | MENTHOL | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|------------------------------|--|---|----------------------|--------------------|
| 1 | NDC:69842-966-06 | 180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | 03/31/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part341 | 03/31/2020 | | |

Labeler - CVS PHARMACY, INC (062312574)

Revised: 9/2023

CVS PHARMACY, INC