

**CVS NIGHTTIME COLD- acetaminophen, dextromethorphan hydrobromide,
doxylamine succinate, and phenylephrine hydrochloride solution
CVS PHARMACY**

CVS Nighttime Cold & Flu Relief

Drug Facts

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Doxylamine succinate 12.5 mg
Phenylephrine HCl 10 mg

Pain reliever/fever reducer
Cough suppressant
Antihistamine
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 4 doses 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
- 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
- trouble urinating due to enlarged prostate gland
- 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.

In case of overdose, get medical help or contact a Poison Control Center right away at 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
- 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 81 mg
- Store at room temperature. Do not refrigerate.

Inactive ingredients

citric acid, D&C Yellow No. 10, disodium edetate, FD&C Blue No. 1, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose

Questions?

1-866-467-2748

Distributed by:

PRINCIPAL DISPLAY PANEL - 354mL Bottle Label

*Compare to the active ingredients in **VICKS® NyQuil™ Severe + VapoCOOL™**

NDC 51316-641-12

NightTime

Cold & Flu Relief

Acetaminophen-Pain reliever/Fever reducer

Dextromethorphan HBr - Cough suppressant

Doxylamine Succinate - Antihistamine

Phenylephrine HCl - Nasal decongestant

For Relief of

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure
- Sneezing, Runny Nose
- Cough

12 FL OZ (354 ml)

***This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil™ Severe+ VapoCOOL™**

3.5625 in
7.25 in

PDP 2.07 in

Drug Facts (continued)

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.

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Questions or comments? 1-866-467-2748

LOT: 61412CVSLR

UNVARNISHED AREA

EXP:

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil™ Severe+VapoCOOL™.

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
© 2023 CVS/pharmacy
CVS.com* 1-800-SHOP CVS V-12431

100% money back guaranteed.
CVS.com/returnpolicy

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

Cooling Severe Nighttime

ACETAMINOPHEN -
Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr-
Cough suppressant

DOXYLAMINE SUCCINATE-
Antihistamine

PHENYLEPHRINE HCl-
Nasal decongestant

Relieves: Minor aches & pains, Fever, Nasal congestion, Sinus pressure, Sneezing, Runny nose, Cough

COLD & FLU

12 FL OZ (354 mL)

Drug Facts TAMPER EVIDENT: DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN.

| 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 & 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.

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CVS NIGHTTIME COLD

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, and phenylephrine hydrochloride solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51316-641 |
| 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: V9BI9B5YI2) (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 |
|--|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| 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 CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | orange | Score | |
| Shape | | Size | |
| Flavor | BERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:51316-641-12 | 354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 01/09/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M010 | 01/09/2023 | |

Labeler - CVS PHARMACY (062312574)