

COOLING SEVERE NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution
CVS Pharmacy

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 Pharmacy, Inc. Cooling Severe Nighttime Drug Facts

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 42 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C blue #1, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose

Questions?

1-800-719-9260

Principal Display Panel

CVS Health®

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

Cooling Severe Nighttime

ACETAMINOPHEN - Pain reliever/Fever reducer

PHENYLEPHRINE HCl - Nasal decongestant

DOXYLAMINE SUCCINATE - Antihistamine

DEXTROMETHORPHAN HBr - Cough suppressant

Relieves:

Minor aches & pains,

Fever, Nasal congestion,

Sinus pressure, Sneezing,

Runny nose, Cough

COLD & FLU

ALCOHOL 10%

12 FL OZ (355 mL)



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

NDC 69842-590-40

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: 59B40 17 F3

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

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Empty & Replace Cap



PLASTIC BOTTLE



PLASTIC CUP

how2recycle.info

Drug Facts

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

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PEEL BACK AT CORNER FOR MORE INFORMATION

: 59B40 17 B1



Drug Facts
(continued)

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Drug Facts
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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

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

ADHESIVE AREA
NO COATING • NO VARNISH • NO TYPE

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NO COATING • NO VARNISH • NO TYPE

COOLING SEVERE NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69842-590 |
| 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 |
| ALCOHOL (UNII: 3K9958V90M) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| 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) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

| Packaging | | | | |
|------------------|------------------|---|-----------------------------|---------------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:69842-590-40 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/20/2019 | |

| Marketing Information | | | |
|------------------------------|---|-----------------------------|---------------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part341 | 06/20/2019 | |

Labeler - CVS Pharmacy (062312574)

