

**NIGHTTIME SEVERE- acetaminophen, dextromethorphan hydrobromide,
doxylamine succinate, phenylephrine hydrochloride solution
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

CVS Pharmacy, Inc. Nighttime Severe Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine Succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- minor aches and pains
- headache
- sore throat
- fever
- runny nose and 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

- 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
- to make a child sleepy

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- glaucoma
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- 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

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

- 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 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 15 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, D&C yellow #10, edetate disodium, FD&C green #3, FD&C red #40, FD&C yellow #6, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions?

1-800-719-9260

Package/Label Principal Display Panel

CVS Health®

Compare to the active ingredients in Vicks® NyQuil® Severe Honey Flavor

Nighttime Severe

ACETAMINOPHEN

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

DOXYLAMINE SUCCINATE

Antihistamine

PHENYLEPHRINE HCl

Nasal decongestant

Relieves:

Fever, Sore throat, Minor aches & pains, Nasal congestion, Sinus pressure, Sneezing, Runny nose, Cough

COLD & FLU

Honey Flavor

12 FL OZ (355 mL)



Compare to the active ingredients in Vicks® NyQuil® Severe Honey Flavor*

NDC 51316-179-40

Nighttime Severe

ACETAMINOPHEN

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

DOXYLAMINE SUCCINATE

Antihistamine

PHENYLEPHRINE HCl

Nasal decongestant

Relieves:

Fever, Sore throat, Minor aches & pains, Nasal congestion, Sinus pressure, Sneezing, Runny nose, Cough

COLD & FLU

Honey Flavor

12 FL OZ (355 mL)

: 86S40 17 F1

Distributed by:
CVS Pharmacy, Inc.
One CVS Drive, Woonsocket,
RI 02895 © 2023 CVS/pharmacy
CVS.com* 1-800-SHOP CVS V-16430
100% money back
guaranteed.
CVS.com/returnpolicy



PARENTS:

Learn about teen medicine abuse
www.StopMedicineAbuse.org

**DO NOT USE IF PRINTED
NECKBAND IS BROKEN
OR MISSING.**

#545974

Drug Facts

Active ingredients (in each 15 mL)

| Active ingredients (in each 15 mL) | Purpose |
|------------------------------------|-----------------------------|
| Acetaminophen 325 mg..... | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg..... | Cough suppressant |
| Doxylamine Succinate 6.25 mg..... | Antihistamine |
| 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 ■ cough to help you sleep ■ minor aches and pains ■ headache ■ sore throat ■ fever ■ runny nose and 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 ■ 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.

PEEL BACK AT
CORNER FOR MORE
INFORMATION

: 86S40 17 B1

Drug Facts (continued)

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 ■ to make a child sleepy

Ask a doctor before use if you have
■ liver disease ■ heart disease
■ high blood pressure ■ glaucoma
■ thyroid disease ■ diabetes
■ cough that occurs with too much

ESIVE AREA
NO VARNISH • NO TYPE

Drug Facts (continued)

■ avoid alcoholic drinks ■ be careful when driving a motorvehicle or operating machinery
■ alcohol, sedatives, and tranquilizers may increase drowsiness

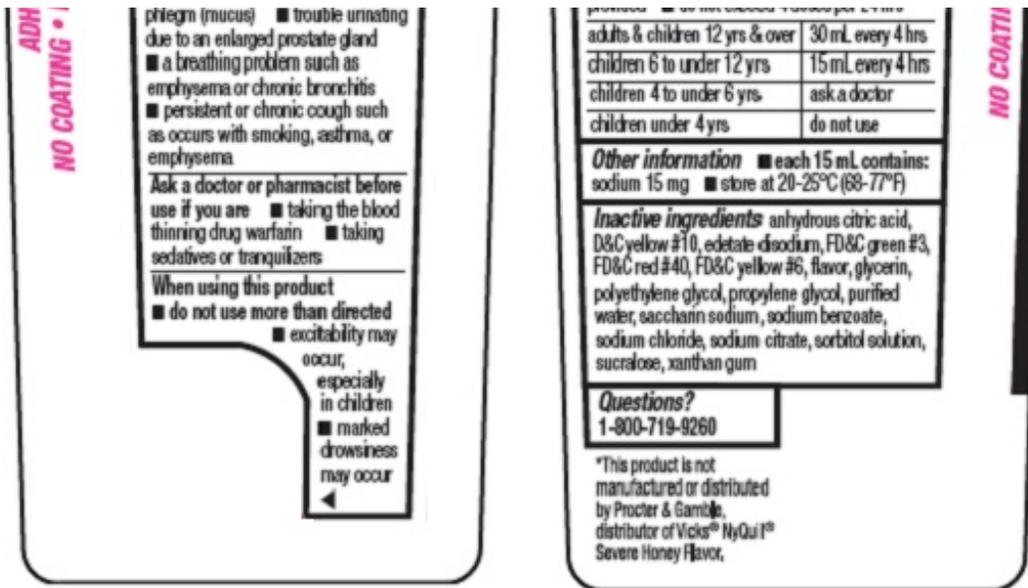
Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults) ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with 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

ADHESIVE AREA
NO VARNISH • NO TYPE



NIGHTTIME SEVERE

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51316-179 |
| 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 |
| DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg in 15 mL |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg in 15 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| 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) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:51316-179-40 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/28/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 06/28/2023 | |

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Revised: 11/2024

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED