

**CVS NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan
hbr, doxylamine succinate solution
CVS PHARMACY**

CVS Nighttime Cold & Flu Relief Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

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.
- 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
- 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 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

- 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

- ◦ pain 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
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- **each 30 mL contains:**sodium 16 mg
- store at room temperature and do not refrigerate

Inactive ingredients

anhydrous citric acid, D&C Yellow No. 10, disodium edetate, FD&C Green No. 3, FD & C Yellow No 6, flavors, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol liquid, sucralose.

Questions or comments?

1-866-467-2748

Package/Label Principal Display Panel

Compare to the active ingredients in VICKS[®] Nyquil[™] Cold & Flu*

NDC 51316-692-12

Nighttime Cold & Flue Relief

Acetaminophen, Dextromethorphan succinate,

Doxylamine HBr

Headache, Fever, Sore Throat

Minor Aches & Pains

Sneezing, Runny Nose, Cough

Original Flavor

12 FL OZ (354 mL)

Distributed by:

This product is not manufactured or distributed by Procter & Gamble, the distributor of Vicks[®] Nyquil[™] Cold & Flu

7.75" Width

3.5" Height

Drug Facts (continued)

When using this product • 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 • pain 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 6 hrs
 children 4 to under 12 yrs ask a doctor
 children under 4 yrs do not use

Other information • each 30 mL contains:
 sodium 16 mg • store at room temperature and do not refrigerate

Inactive ingredients citric acid, D&C Yellow No. 10, disodium edetate, FD&C Green No. 3, FD&C Yellow No. 6, flavors, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol liquid, sucralose.

Questions or comments? 1-866-467-2748

LOT: 6920R612CVSR
 UNVARNISHED
 AREA
 EXP:
 Distributed by: **CVS Pharmacy, Inc.**
 One CVS Drive
 Woonsocket, RI 02896
 © 2023 CVS/pharmacy
 CVS.com™ 1-800-SHOP CVS
 1-V-12431
 100% money back
 guaranteed.
 CVS.com/returnpolicy
 Dispensed from
 Recycled Glass
 Recycled Caps
 PLASTIC BOTTLE
 PLASTIC CUP
 100% recycled plastic



Compare to the active ingredients in Vicks® NyQuil™ Cold & Flu*

Multi-Symptom Nighttime

ACETAMINOPHEN- Pain reliever; Fever reducer
DEXTROMETHORPHAN HBr- Cough suppressant
DOXYLAMINE SUCCINATE- Antihistamine

Relieves:
 Headache, Fever, Sore throat,
 Minor aches & pains, Sneezing,
 Runny nose, Cough

COLD & FLU
 Original Flavor

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 30 mg	Cough suppressant
Doxylamine succinate 12.5 mg	Antihistamine

Uses: temporarily relieves common cold/flu symptoms:
 • cough due to minor throat and bronchial irritation • sore throat • headache
 • minor aches and pains • fever • runny nose and sneezing

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 • 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 an enlarged prostate gland

Ask a doctor or pharmacist before use if you are • taking sedatives or tranquilizers • taking the blood thinning drug warfarin

CVS NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-692
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	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 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 YELLOW NO. 6 (UNII: H77VEI93A8)	
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)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-692-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/13/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	02/13/2023	

Labeler - CVS PHARMACY (062312574)

Revised: 8/2024

CVS PHARMACY