

**NIGHTTIME COLD AND FLU- acetaminophen, diphenhydramine hci,
phenylephrine hci liquid
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.

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves there symptoms due to a cold
 - minor aches and pains
 - headache
 - sore throat
 - runny nose
 - sneezing
 - itchy, watery eyes due to hay fever
 - nasal and sinus congestion
 - itching of the nose or throat
 - cough due to minor throat and bronchial irritation
- temporarily reduces fever

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

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

- to make a child sleepy
- 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.
- with any other product containing diphenhydramine, even one used on skin
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease
- glaucoma
- heart disease
- thyroid disease
- high blood pressure
- 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
- sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcohol drinks
- be careful when driving a motor vehicle or operating machinery
- marked drowsiness may occur
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 6 doses (180 mL) in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- mL=milliliter
- keep dosing cup with product
- adults and children 12 years and over
 - 30 mL every 4 hours
- children under 12 years of age; do not use

Other information

- **each 30 mL contains:** potassium 10 mg
- **each 30 mL contains:** sodium 14 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

acesulfame potassium, alcohol, citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavors, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate

Principal Display Panel

Compare to the active ingredients in Theraflu® ExpressMax® Nighttime Severe Cold & Cough*

Severe Cold & Cough relief

ACETAMINOPHEN

Pain reliever; Fever reducer

DIPHENHYDRAMINE HCl

Antihistamine; Cough Suppressant

PHENYLEPHRINE HCl

Nasal decongestant

Relief of:

Nasal congestion; Runny nose; Cough; Fever; Body ache; Sore throat; Headache

NIGHTTIME

Berry Flavor

Alcohol content 10%

For Ages 12 & Over

FL OZ (mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

*This product is not manufactured or distributed by GSK Consumer Health, distributor Theraflu® ExpressMax® Nighttime Severe Cold & Cough.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

Product Label



Compare to the active ingredients
in Theraflu® ExpressMax®
Nighttime Severe Cold & Cough*

Severe Cold & Cough

NDC 59779-693-08

ACETAMINOPHEN

Pain reliever; Fever reducer

DIPHENHYDRAMINE HCl

Antihistamine; Cough suppressant

PHENYLEPHRINE HCl

Nasal decongestant

Relief of:

Nasal congestion; Runny nose;
Cough; Fever; Body ache;
Sore throat; Headache

NIGHTTIME



Berry Flavor
Alcohol content 10%
For Ages 12 & Over

8.3 FL OZ (245 mL)

PLD-13398
LB008862

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY
SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.**

*This product is not manufactured or distributed by GSK
Consumer Healthcare, distributor of Theraflu® ExpressMax®
Nighttime Severe Cold & Cough.

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CVS.com® 1-800-SHOP CVS V-13114

#455443



PLD-C3998
LB008865

0 50428 25333 5

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg.....Pain reliever/fever reducer
Diphenhydramine HCl 25 mg.....Antihistamine/
Cough suppressant
Phenylephrine HCl 10 mg.....Nasal decongestant

Purposes

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

Uses

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If a skin reaction occurs, stop use and seek medical help right away.

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Drug Facts (continued)

Do not use to make a child sleepy

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Inactive ingredients acesulfame potassium, alcohol, citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, maltitol, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

CVS HEALTH Severe Cold & Cough Berry Flavor

NIGHTTIME COLD AND FLU

acetaminophen, diphenhydramine hci, phenylephrine hci liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-693
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
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-693-08	245 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/03/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/03/2022	

Labeler - CVS Pharmacy (062312574)