

**NIGHTTIME COLD AND FLU MULTI SYMPTOM RELIEF- acetaminophen,
dextromethorphan hbr, doxylamine succinate liquid
Shield Pharmaceuticals Corp**

Nighttime Cold and Flu Multi-Symptom Relief

Drug Facts

Active ingredient (in each softgel)

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 & bronchial irritation
- sore throat
- headache • minor aches & pains • fever • runny nose & sneezing

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 Softgels in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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 enlarged prostate gland

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 n 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, & 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
- 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 (1-800-222-1222) right away. Quick medical attention is critical for adults & 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 24 mg
- store between 20-25°C (68-77°F) and do not refrigerate.

Inactive ingredients

alcohol, citric acid, FD&C Blue No. 1, FD&C Red No. 40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol, sucralose,

xanthan gum

Questions or comments?

1-800-373-6981(toll-free)

Distributed by:
Shield Pharmaceuticals Corp.
Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL

ValuRx

Nighttime Cold & Flu
Multi-Symptom Relief

Label

ValuRx

Compare to the Active Ingredients in Vicks® NyQuil® Cold & Flu*

Nighttime Cold & Flu

Multi-Symptom Relief

Acetaminophen- Pain reliever/Fever reducer

Dextromethorphan HBr- Cough suppressant

Doxylamine succinate- Antihistamine

4 fl. oz. (118 mL)

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

Drug Facts

Active ingredients (in each 15 mL)

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 & bronchial irritation ■sore throat ■headache ■minor aches & 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.

Drug Facts (continued under label)

* This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademarks Vicks® NyQuil® Cold & Flu.

Made in India

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06/10/2024

Distributed by:

Shield Pharmaceuticals Corp.

Hauptaug, NY 11788

LOT:

EXP:

Drug Facts (continued)

Sore throat warning:

If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use

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■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 enlarged prostate gland

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■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 or comments?

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Compare to the Active Ingredients in Vicks® NyQuil® Cold & Flu*

Nighttime Cold & Flu

\$125

Multi-Symptom Relief

Acetaminophen-
Pain reliever/Fever reducer
Dextromethorphan HBr-
Cough suppressant
Doxylamine succinate-
Antihistamine

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Drug Facts (continued under label)

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Made in India

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LOT: EXP:

Distributed by:
Shield Pharmaceuticals Corp.
Hempstead, NY 11798

06/18 06/2024

NIGHTTIME COLD AND FLU MULTI SYMPTOM RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83059-0125
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 118 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 118 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 118 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3Z D4)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	green	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0125-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/24/2026	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	01/24/2026		

Labeler - Shield Pharmaceuticals Corp (118724924)

Registrant - Shield Pharmaceuticals Corp (118724924)