

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

Nighttime Cold and Flu

Drug Facts

Active ingredient (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 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**
- **do not exceed 8 softgels per 24 hrs**
- adults & children 12 yrs & over 2 Softgels with water every 6 hrs
- children 4 to under 12 yrs ask a doctor
- children under 4 yrs do not use

Other information

- store between 20-25°C (68-77°F).

Avoid high humidity and excessive heat.

Protect from light.

Questions or comments?

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

Inactive ingredients

butylated hydroxyanisole, D&C Yellow No. 10*, FD&C Blue No. 1, gelatin, glycerin, methyl paraben, polyethylene glycol-400, propylene glycol, propylparaben, povidone, purified water, sorbitol *may contain this inactive ingredient

Distributed by:

Shield Pharmaceuticals Corp.

Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL

ValuRx

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

Nighttime Cold & Flu

Multi-Symptom Relief

Acetaminophen

Dextromethorphan HBr

Doxylamine succinate

- Headache, Fever, Sore Throat,
- Minor Aches & Pain
- Sneezing, Runny Nose
- Cough

Carton



NIGHTTIME COLD AND FLU MULTI SYMPTOM RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83059-0112
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)				
Product Characteristics				
Color	green	Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	SD26;SDN	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0112-1	1 in 1 CARTON	11/12/2025	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	11/12/2025		
Labeler - Shield Pharmaceuticals Corp (118724924)				