

**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, FD&C Blue No. 1, gelatin, glycerin, methyl paraben, polyethylene glycol-400, propylene glycol, propyl Paraben, povidone, purified water, sorbitol

Distributed by:

**Shield Pharmaceuticals Corp.**

Hauppauge, NY 11788

**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:83059-0024
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	SD26
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0024-1	1 in 1 CARTON	04/06/2024	
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	04/06/2024	

**Labeler -** Shield Pharmaceuticals Corp (118724924)

Revised: 4/2024

Shield Pharmaceuticals Corp