

**MAXIMUM STRENGTH NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled  
Prodose, Inc.**

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**Maximum Strength Nighttime Severe Cold and Flu**

***Drug Facts***

***Active ingredients (in each Softgel)***

Acetaminophen 325mg

Dextromethorphan HBr 10mg

Doxylamine succinate 6.25mg

Phenylephrine HCl 5mg

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

***Uses***

- temporarily relieves common cold/flu symptoms
- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever

- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

## **Warnings**

**Liver warning** This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 8 softgels 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
- heart disease
- high blood pressure
- thyroid disease

- diabetes
- 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
- excitability may occur, especially in children
- marked drowsiness may occur n 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**

- you get nervous, dizzy or sleepless
- pain, nasal congestion, 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. 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
- do not exceed 8 softgels per 24 hour

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adults & children 12 years & over	2 softgels with water every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

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**Other information**

- do not exceed 25°C (77°F)

### ***Inactive Ingredients***

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, sodium hydroxide\*, titanium dioxide

\* may contain this ingredient

### ***Questions or comments?***

**1-888-333-9792**

### **Principal Display Panel**

Compare to Vicks® NyQuil® Severe Cold & Flu active ingredients†

Maximum Strength

Nighttime

Severe Cold and Flu

- Relieves headache, fever, sore throat,

minor aches & pains, nasal/sinus

congestion & sinus pressure, sneezing, runny nose & cough

10 Softgels



## MAXIMUM STRENGTH NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4210
<b>Route of Administration</b>	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	10 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)
<b>GELATIN</b> (UNII: 2G86QN327L)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>POVIDONE</b> (UNII: FZ989GH94E)
<b>SORBITOL</b> (UNII: 506T60A25R)
<b>SORBITAN</b> (UNII: 6O921CV9RU)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	116;A07
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4210-1	1 in 1 CARTON	08/19/2022	
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	08/19/2022	

**Labeler** - Prodose, Inc. (119371190)