

**DG HEALTH NIGHTTIME SEVERE COLD AND FLU- acetaminophen,  
dextromethorphan hydrobromide, doxylamine succinate, phenylephrine  
hydrochloride capsule  
Dolgenercorp Inc**

*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.*

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**NightTime SEVERE Cold & Flu Relief**

***Drug Facts***

***Active ingredients (in each softgel)***

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Doxylamine succinate 6.25 mg  
Phenylephrine HCl 5 mg

***Purposes***

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 • a sodium-restricted diet • trouble urinating due to enlarged prostate gland • 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

### **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
- 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.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away.

### **Directions**

- take only as directed
- do not exceed 8 softgels per 24 hrs

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

### Other information

- store at 20-25°C (68-77°F) • protect from light, heat and moisture

### Inactive ingredients

edible printing ink, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

### Questions or comments?

Call **1-888-577-8033** Monday - Friday 8am - 4pm EST

**COMPARE TO VICKS® NYQUIL® SEVERE COLD & FLU ACTIVE INGREDIENTS\*  
MULTI-SYMP TOM RELIEF  
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

\*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademarks Vicks® and NyQuil™.

**TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.**

Distributed by:  
Strive Pharmaceuticals Inc.  
East Brunswick, NJ 08816  
Product of United Arab Emirates

### Packaging



# Night Time

## SEVERE Cold & Flu Relief

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN  
 COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr  
 ANTIHISTAMINE - DOXYLAMINE SUCCINATE  
 NASAL DECONGESTANT - PHENYLEPHRINE HCl

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sinus Congestion & Pressure
- Sneezing & Runny Nose
- Cough



actual size

24 SOFTGELS

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND DIRECTIONS

**Drug Facts**

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 Dextromethorphan HBr 10 mg  
 Doxylamine succinate 6.25 mg  
 Phenylephrine HCl 5 mg

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- temporarily restores freer breathing through the nose
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■ 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 ■ diabetes ■ glaucoma ■ a sodium-restricted diet

- taking the blood thinning drug warfarin

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**Directions**

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

**Drug Facts (continued)**

**Other information** ■ store at 20-25°C (68-77°F) ■ protect from light, heat and moisture

**Inactive ingredients:** soluble printing ink, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 40 propylene glycol, purified water, sodium sorbitan sebacate

**Questions or comments?** Call 1-888-577-8033 Monday - Friday 8am - 4pm EST

\*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark REVOL

Distributed by: Shive Pharmaceuticals Inc. East Brunswick, NJ 08816

Product of United Arab Emirates

LOT: COATING FREE AREA  
 EXP:



### DRUG FACTS TABLE

**Drug Facts**

**Active ingredients (in each softgel)**

Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

**Purposes**

**Drug Facts (continued)**

**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
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- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression

**Drug Facts (continued)**

- trouble urinating due to enlarged prostate gland
- 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

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adults & children 12 yrs & over	2 softgels with water every 4 hours
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children under 4 yrs	do not use

■ do not exceed 8 softgels per 24 hrs

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**Drug Facts** (continued)

**Other information** ■ store at 20-25°C (68-77°F) ■ protect from light, heat and moisture

**Inactive ingredients** edible printing ink, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

**Questions or comments?** Call 1-888-577-8033 Monday - Friday 8am - 4pm EST

## DG HEALTH NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-286
<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 HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B6978945GQ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
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<b>Shape</b>	OVAL (oblong)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	812
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-286-24	2 in 1 CARTON	08/08/2023	
1		12 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 final	part341	08/08/2023	

**Labeler** - Dolgencorp Inc (068331990)

Revised: 8/2023

Dolgencorp Inc