

**DR. SIMI NIGHTTIME COLD AND FLU- acetaminophen 325 mg,  
dextromethorphan hbr 15 mg, doxylamine succinate 6.25 mg capsule, liquid  
filled  
Farmacias De Similares TX LLC**

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**Dr. Simi Nighttime Cold & Flu**

***Drug Facts***

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

Acetaminophen 325 mg  
Dextromethorphan HBr 15 mg  
Doxylamine succinate 6.25 mg

***Purpose***

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Acetaminophen 325 mg	Pain reliever/ fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

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***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 exceed recommended dosage**
- 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
  - 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 accidental overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as children, even if you do not notice any signs or symptoms.

### ***Directions***

- take only as directed (see Warnings)
- do not exceed 4 doses per 24 hrs

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adults & children 12 years and over	2 softgels with water every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

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■ **When using other daytime or nighttime products, carefully read each label to ensure correct dosing**

### ***Other information***

- Store at room temperature 20-25°C (68-77°F)
- avoid excessive heat

### ***Inactive ingredients***

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

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

855-280-1079

### **Principal Display Panel**

**NDC: 85786-602-24**

DR. SIMI

Nighttime Cold & Flu

Acetaminophen,  
Dextromethorphan HBr,  
Doxylamine Succinate

Pain Reliever / Fever Reducer  
Cough Suppressant & Antihistamine

# Multi-Symptom Relief: Aches, Fever, Sore Throat, Cough, Sneezing & Runny Nose

24 Softgels

\*Compare to the active ingredients in Vicks® NyQuil™ Cold & Flu Nighttime Relief LiquiCaps™

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

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

Distributed by: FARMACIAS DE SIMILARES TX LLC

800 Brazos St Ste 260, Austin, TX, 78701, USA

customerservice@drsimi.com

www.drsimi.com

## Carton labeling

**Drug Facts**  
**Active ingredients (in each softgel)**  
 Acetaminophen 325 mg.....Pain reliever/fever reducer  
 Dextromethorphan HBr 15 mg.....Cough suppressant  
 Doxylamine succinate 6.25 mg.....Antihistamine

**Purpose**  
 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.  
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**Drug Facts (continued)**  
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**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  
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 taking sedatives or tranquilizers taking the blood thinning drug warfarin  
**When using this product**  
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**Drug Facts (continued)**  
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**Questions or comments?**  
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**DR. SIMI+**  
 NDC: 85786-602-24  
 \*Compare to the active ingredients in Vicks® NyQuil™ Cold & Flu Nighttime Relief LiquiCaps™

**Nighttime Cold & Flu**  
**Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate**  
**Pain Reliever / Fever Reducer Cough Suppressant & Antihistamine**  
**Multi-Symptom Relief:**  
 Aches, Fever, Sore Throat, Cough, Sneezing & Runny Nose

**24 softgels**

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.**  
**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**  
 Failure to follow these warnings could result in serious consequences.

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## DR. SIMI NIGHTTIME COLD AND FLU

acetaminophen 325 mg, dextromethorphan hbr 15 mg, doxylamine succinate 6.25 mg capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85786-602
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	

**Product Characteristics**

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oblong softgel capsule)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	604
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85786-602-24	2 in 1 CARTON	03/30/2026	
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 Drug	M012	03/30/2026	

**Labeler** - Farmacias De Similares TX LLC (119489934)**Establishment**

Name	Address	ID/FEI	Business Operations
AptaPharma, Inc.		790523323	manufacture(85786-602)

Revised: 3/2026

Farmacias De Similares TX LLC