

**DR. SIMI DAYTIME COLD AND FLU- acetaminophen 325 mg,
dextromethorphan hbr 10 mg, phenylephrine hcl 5 mg capsule, liquid filled
Farmacias De Similares TX LLC**

Dr. Simi Daytime Cold & Flu

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

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

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever

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
- thyroid disease
- high blood pressure
- trouble urinating due to enlarged prostate gland
- heart disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product

do not use more than directed.

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- nervousness, dizziness, or sleeplessness occur
- 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

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

• **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

FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

855-280-1079

Principal Display Panel

NDC: 85786-601-12

DR. SIMI

Daytime Cold & Flu

Acetaminophen,
Dextromethorphan HBr,
Phenylephrine HCl

Pain Reliever / Fever Reducer
Cough Suppressant & Nasal Decongestant

Multi-Symptom Relief. Aches, Fever, Sore Throat, Cough, Nasal Congestion, Sinus Pressure

12 Softgels

*Compare to the active ingredients in Vicks® DayQuil™ Cold & Flu LiquiCaps™

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil™ LiquiCap™.

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
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customerservice@drsimi.com
www.drsimi.com

Carton Labeling

<p>Drug Facts</p> <p>Active ingredients (in each softgel)</p> <p>Acetaminophen 325 mg.....Pain reliever/fever reducer Dextromethorphan HBr 10 mg.....Cough suppressant Phenylephrine.....Nasal decongestant HCl 5 mg.....Nasal decongestant</p> <p>Purpose</p> <p>temporarily relieves common cold/flu symptoms: nasal congestion, cough due to minor throat & bronchial irritation, sore throat, headache, minor aches & pains, fever</p> <p>Warnings</p> <p>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 or 3 or more alcoholic drinks daily while using this product</p> <p>Allergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash. If a skin reaction occurs, stop use and seek medical help right away.</p> <p>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.</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 	<p>Drug Facts (continued)</p> <p>doctor or pharmacist before taking this product.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> liver disease heart disease thyroid disease diabetes high blood pressure trouble urinating due to enlarged prostate gland cough that occurs with too much phlegm (mucus) persistent or chronic cough as occurs with smoking, asthma or emphysema <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <p>When using this product, do not use more than directed.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> pain, cough, or nasal congestion gets worse or lasts more than 7 days nervousness, dizziness, or sleeplessness occur 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. <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> take only as directed (see Warnings) do not exceed 4 doses per 24 hrs <table border="1"> <tr> <td>adults & children 12 years and over</td> <td>2 softgels with water every 4 hours</td> </tr> <tr> <td>children 4 to under 12 years.</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 years</td> <td>do not use</td> </tr> </table>	adults & children 12 years and over	2 softgels with water every 4 hours	children 4 to under 12 years.	ask a doctor	children under 4 years	do not use	<p>Drug Facts (continued)</p> <p>When using other daytime or nighttime products, carefully read each label to ensure correct dosing</p> <p>Other information</p> <ul style="list-style-type: none"> store at room temperature 20-25° C (68-77° F). avoid excessive heat <p>Inactive ingredients FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide.</p> <p>Questions or comments? 855-280-1079</p> <p><small>*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil™ LiquiCap™.</small></p>	<p style="text-align: right;">NDC: 85786-601-12</p> <p style="text-align: center;">*Compare to the active ingredients in Vicks® DayQuil™ Cold & Flu LiquiCaps™</p> <p style="text-align: center;">DR. SIMI </p> <p style="text-align: center;">Daytime Cold & Flu</p> <p style="text-align: center;">Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl</p> <p style="text-align: center;">Pain Reliever / Fever Reducer Cough Suppressant & Nasal Decongestant</p> <p style="text-align: center;">Multi-Symptom Relief: Aches, Fever, Sore Throat, Cough, Nasal Congestion, Sinus Pressure</p> <p style="text-align: center;">12 Softgels</p>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Distributed by: FARMACIAS DE SIMILARES TX LLC 800 Brazos St Ste 260, Austin, TX, 78701, USA customerservice@drsimi.com www.drsimi.com</p>
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DR. SIMI DAYTIME COLD AND FLU

acetaminophen 325 mg, dextromethorphan hbr 10 mg, phenylephrine hcl 5 mg capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85786-601
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL (Oblong softgel capsule)	Size	20mm
Flavor		Imprint Code	603
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85786-601-12	1 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(85786-601)

Revised: 3/2026

Farmacias De Similares TX LLC