

**SEVERE DAYTIME COLD AND FLU DAYTIME MAXIMUM STRENGTH NON-DROWSY SEVERE- acetaminophen, guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled Walgreens**

**DAYTIME NON-DROWSY MAXIMUM STRENGTH SEVERE COLD & FLU**

**Drug Facts**

<b>Active ingredients (in each softgel)</b>	<b>Purpose</b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- minor aches & pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses 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
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, 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**

- 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**

Taking more than directed can cause serious health problems. 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 - see **Overdose warning**
- do not exceed 4 doses per 24 hours

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

- **when using other Nighttime or Daytime products, carefully read each label to ensure correct dosing**

## Other information

- store at room temperature

## Inactive ingredients

FD&C Yellow # 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

## Questions or comments?

**Call toll free: 1-888-333-9792**

## PRINCIPAL DISPLAY PANEL

Walgreens

Compare to Vicks® DayQuil® Severe

Cold&Flue active ingredients††

DAYTIME NON-DROWSY

Severe Cold & Flu

ACETAMINOPHEN/ACHES/ FEVER/ SORE THROAT

DEXTROMETHORPHAN HBr/ COUGH SUPPRESSANT

GUAIFENESIN/ EXPECTORANT

PHENYLEPHRINE HCL/NASAL DECONGESTANT

MAXIMUM STRENGTH

Relieves headache, fever, sore throat,

minor aches & pains, cough, chest congestion,

nasal/sinus congestion & sinus pressure

24

SOFTGELS

The image shows the front of a Walgreens box for Severe Cold & Flu Daytime Non-Drowsy Softgels. The box is primarily orange and red. At the top, the Walgreens logo is in white script on a red background. Below the logo, the text 'DAYTIME NON-DROWSY' is in white, followed by 'Severe Cold & Flu' in large white font. A grey callout bubble says 'Compare to Vicks® DayQuil® Severe Cold & Flu active ingredients†'. The NDC number 'NDC 0363-8996-24' is printed in white. The active ingredients are listed in white: 'ACETAMINOPHEN 325 mg / PAIN RELIEVER / FEVER REDUCER', 'DEXTROMETHORPHAN HBr 10 mg / COUGH SUPPRESSANT', 'GUAIFENESIN 200 mg / EXPECTORANT', and 'PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT'. A grey bar with a checkmark icon contains the text 'DISSOLVES QUICKLY'. Below this, a grey bar says 'MAXIMUM STRENGTH'. A list of symptoms is shown: 'Relieves headache, fever, sore throat, minor aches & pains, cough, chest congestion, nasal/sinus congestion & sinus pressure'. A large white '24' is followed by 'SOFTGELS' in white. A large, empty rounded rectangle is on the right side of the box.

**SEVERE DAYTIME COLD AND FLU DAYTIME MAXIMUM STRENGTH  
NON-DROWSY SEVERE**

acetaminophen, guaifenesin, dextromethorphan hydrobromide, and phenylephrine hydrochloride  
capsule, liquid filled

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:0363-8996

<b>Route of Administration</b>	ORAL
--------------------------------	------

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<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)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL (OBLONG)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	341;908
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-8996-24	2 in 1 CARTON	08/23/2021	
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	08/23/2021	

