

**ACETAMINOPHEN DEXTROMETHORPHAN HBR DOXYLAMINE SUCCINATE  
PHENYLEPHRINE HCL- acetaminophen dextromethorphan hbr doxylamine succinate  
phenylephrine hcl capsule, liquid filled  
CVS PHARMACY,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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**Severe Non-Drowsy  
Sinus Congestion and Cough Relief**

**Acetaminophen 325 mg each  
Dextromethorphan hydrobromide 10 mg each  
Phenylephrine hydrochloride 5 mg each**

**Severe  
Sinus Congestion and Cough Relief**

**Acetaminophen 325 mg each  
Dextromethorphan hydrobromide 10 mg each  
Doxylamine succinate 6.25 mg each  
Phenylephrine hydrochloride 5 mg each**

**Active ingredients**

***Severe Sinus Congestion & Cough Relief Day***

(in each Softgel)

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Acetaminophen	325 mg
Dextromethorphan hydrobromide	10 mg
Phenylephrine hydrochloride	5 mg

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**Purposes**

Pain reliever/fever reducer  
Cough suppressant  
Nasal decongestant

**Uses**

temporarily relieves these symptoms due to cold and flu:

- sneezing
- itching of the nose, throat or watery eyes due to hay fever
- cough
- nasal congestion
- sinus congestion and pressure
- sore throat
- head ache
- minor aches and pains

helps clear nasal passages and shrinks swollen membranes

temporarily reduces fever

## **Warnings**

### **Liver warning**

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

- more than 10 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 or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- hives
- facial swelling
- asthma (wheezing)
- shock

If a skin or allergic 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.
- if you ever had an allergic reaction to this product or any of its ingredients.
- in children 12 years of age.

### **Ask a doctor before use if you have**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough with excess phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough 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 exceed recommended dosage**

### **Stop use and ask a doctor if**

- pain, cough, or nasal congestion 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 head ache that lasts for 1 week, these could be the signs of serious condition
- nervousness, dizziness, or sleeplessness occurs

### **If pregnant or breast-feeding**

ask a health professional before use.

### **Keep out of the reach of children**

In case of overdose, get medical help or contact 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**

#### **Do not take more than the recommended dose**

adults & children under 12 years and over

- take 2 softgels with water every 4 hours.
- do not exceed 10 softgels in 24 hours or as directed by a doctor

children under 12 years

- do not use

### **Other information**

- store in a cool and dry place.
- protect from sunlight.
- **Parents: Learn about teen medicine abuse, [WWW.StopMedicineAbuse.org](http://WWW.StopMedicineAbuse.org)**

### **Inactive ingredients**

FD&C Blue 1, FD&C Red 40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan, titanium dioxide

### **Questions or comments?**

call **1-877-770-3183** Mon-Fri 9:00 AM to 4:30 PM EST

### **Active ingredients**

***Severe Sinus Congestion & Cough Relief Night***

***(in each Softgel)***

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Acetaminophen	325 mg
Dextromethorphan hydrobromide	10 mg
Doxylamine succinate	6.25 mg
Phenylephrine hydrochloride	5 mg

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**Purposes**

Pain reliever/fever reducer  
Cough suppressant  
Antihistamine  
Nasal decongestant

**Uses**

temporarily relieves these symptoms due to cold and flu:

- sneezing
- itching of the nose, throat or watery eyes due to hay fever
- cough
- nasal congestion
- sinus congestion and pressure
- sore throat
- headache
- minor aches and pains
- runny nose

helps clear nasal passages and shrinks swollen membranes  
temporarily reduces fever

**Warnings**

**Liver warning**

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- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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- blisters
- rash
- hives
- facial swelling
- asthma (wheezing)
- shock

If a skin or allergic 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.

## **Warnings**

### **Do not use to sedate children**

### **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.
- if you ever had an allergic reaction to this product or any of its ingredients.
- in children 12 years of age.

### **Ask a doctor before use if you have**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough with excess phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough occurs with smoking, asthma, or emphysema

### **Ask a doctor or pharmacist before use if you are**

- taking sedatives or tranquilizers
- taking a blood thinning drug warfarin

### **When using this product**

- **do not exceed recommended dose**
- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving motor vehicles or operating machinery
- may cause excitability in children

### **Stop use and ask a doctor if**

- pain, cough, or nasal congestion 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 head ache that lasts for 1 week, these could be the signs of serious condition
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adults & children under 12 years and over

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- children under 12 years
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### Other information

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**Severe Non-drowsy  
 Sinus Congestion  
 & Cough Relief**

**ACETAMINOPHEN 325 mg each**  
 Pain reliever - Fever reducer  
**DEXTROMETHORPHAN HBr 10 mg each**  
 Cough suppressant  
**PHENYLEPHRINE HCl 5 mg each**  
 Nasal decongestant

**Relieves:**  
 Nasal & Sinus  
 Congestion,  
 Sinus Pressure,  
 Headache &  
 Body Ache,  
 Cough



Actual Size

**12 SOFTGELS**

Compare to the active ingredients in Alka-Seltzer PLUS® Day & Night Severe Sinus Congestion & Cough Liquid Gels\*

**Sinus Congestion & Cough**

**Severe  
 Sinus Congestion  
 & Cough Relief**

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 Antihistamine  
**PHENYLEPHRINE HCl 5 mg each**  
 Nasal decongestant

**Relieves:**  
 Sinus Congestion  
 & Pressure,  
 Headache & Pain,  
 Runny Nose &  
 Sneezing, Cough



Actual Size

**8 SOFTGELS  
 TOTAL 20 SOFTGELS**

#234944



COATING FREE AREA

Lot  
 Exp.

**Important: Read all product information before using. Keep the carton for important information.  
 DO NOT USE IF BLISTER IS CUT OR BROKEN.**

**Severe Sinus Congestion  
 & Cough Relief Night**

**Drug Facts**  
**Active ingredients**  
 (in each softgel)  
 Acetaminophen 325 mg.....Pain reliever/fever reducer  
 Dextromethorphan hydrobromide 10 mg.....Cough suppressant  
 Doxylamine succinate 6.25 mg.....Antihistamine  
 Phenylephrine hydrochloride 5 mg.....Nasal decongestant

**Uses**  
 Temporarily relieves these symptoms due to cold and flu:  
 sneezing  
 itching of the nose, throat or watery eye due to hay fever  
 nasal congestion  
 sinus congestion and pressure  
 sore throat  
 headache  
 minor aches and pains

**Warnings**  
 Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 10 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 or severe allergic reactions. Symptoms may include:  
 skin redness  
 blisters  
 rash  
 hives  
 facial swelling  
 asthma (wheezing)  
 shock

**Drug Facts (continued)**  
 If a skin or allergic reaction occurs, stop use and seek medical help right away.  
 Some 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.

**Severe Sinus Congestion  
 & Cough Relief Day**

**Drug Facts**  
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 (in each softgel)  
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# ACETAMINOPHEN DEXTROMETHORPHAN HBR DOXYLAMINE SUCCINATE PHENYLEPHRINE HCL

acetaminophen dextromethorphan hbr doxylamine succinate phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-305
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
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg



## Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	green (Nighttime) , blue (Daytime)	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	314;116
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-305-02	20 in 1 PACKAGE, COMBINATION	07/07/2017	
1		8 in 1 BLISTER PACK		
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	07/07/2017	

**Labeler** - CVS PHARMACY,INC (062312574)

Revised: 7/2017

CVS PHARMACY,INC