

**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 and 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

### **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 have**

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 at controlled room temperature, 15 – 30°C (59 – 86°F)
- **Parents: Learn about teen medicine abuse, [WWW.StopMedicineAbuse.org](http://WWW.StopMedicineAbuse.org)**

#### **Inactive ingredients**

allura red AC, butylated hydroxyanisole, butylated hydroxytoluene, gelatin, glycerol, polyethylene glycol, povidone, propylene glycol, purified water, sorbital sorbitan solution, sunset yellow FCF

#### **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

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

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- 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 to sedate children.**

**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**

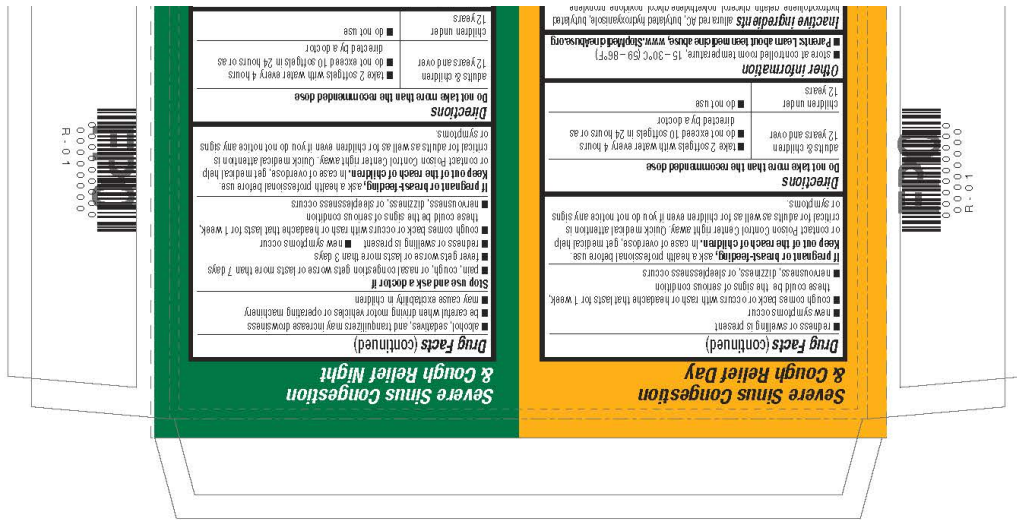
- **do not exceed recommended dose**
- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving motor vehicles or operating machinery
- may cause excitability in children

## **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







PLEASE LEAVE OUR CVS SLUG ON ALL FINAL ART AND CONTRACT PROOFS FOR FINAL APPROVAL

 <p>Store Brands Packaging Group 68 Cumberland Street, Ste 200 Woonsocket, RI 02895</p> <p>Please direct questions &amp; proofs to: Alyssa.Kelly@sgsco.com Phone: 401-531-2306</p> <p>DATE: 10/09/2017 VENDOR: GRANULES BRAND: CVS 1 COLD REMEDIES FILE NAME: 18_HCB_234944_SVR3NSGSGTNT_2007 ITEM NUMBER: 234944 UPC#: 050428366820 PA ARTIST: AH</p>	<p><b>VENDOR PRE-PRESS RESPONSIBILITIES</b></p> <ul style="list-style-type: none"> <li>CONFIRMATION OF COLOR SPECS AS NEEDED FOR PROPER SEPARATIONS.</li> <li>TRAPPING, BLEED AND MINIMUM TOLERANCE ADJUSTMENTS TO MEET TARGET PRESS REQUIREMENTS.</li> <li>REPLACE UPC WITH PROPER BWR PER PRINTER SPECS, ENSURE UPC SCANS ARE CORRECT.</li> </ul>	<p><b>PRODUCTION SPECIFICATIONS</b></p>  <p><b>TARGET COLOR, PRINT AS 4C IF NECESSARY</b></p>  <p>4C CONV. OF PMS 186: C=0, M=100, Y=81, K=4</p> <p>WHITE CARTON</p>	<p><b>NOTES AND AREAS OF FOCUS</b></p> <p>ADDITIONAL SPOT COLORS ARE BRAND CRITICAL AND MUST NOT BE CONVERTED AND PRODUCED WITH PROCESS EQUIVALENT PROXY COLORS. COLOR SEPARATION SPECIFICATION SHOULD MATCH CVS PRINT QUOTATION FOR THIS JOB.</p>
	<p><b>LINKED IMAGE ASSETS</b></p> <p>SHUTTERSTOCK_111345781 PSD SHUTTERSTOCK_128143409.JPG</p>	<p><b>VENDOR PROOFING REQUIREMENTS</b></p> <p>PDF CONTENT PROOF AND SUBSEQUENT CONTRACT PROOF PER PROJECT SCHEDULE.</p>	

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**PA 01**  
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# ACETAMINOPHEN DEXTROMETHORPHAN HBR DOXYLAMINE SUCCINATE PHENYLEPHRINE HCL

acetaminophen dextromethorphan hbr doxylamine succinate phenylephrine hcl capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-303
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	PHENYLEPHRINE	5 mg



UNII:1WS297W6MV)	HYDROCHLORIDE	5 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
SORBITAN (UNII: 6O92ICV9RU)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

### Product Characteristics

Color	green, orange (534 (Daytime))	Score	no score
Shape	OVAL (Orange (Daytime) Green (Nighttime))	Size	20mm
Flavor		Imprint Code	534
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-303-02	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/30/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/30/2017	

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