

**DAYTIME CONGESTION PRESSURE AND PAIN- acetaminophen, phenylephrine hydrochloride 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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**Daytime Congestion, Pressure & Pain**

**Active ingredients (in each softgel)**

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

**Purpose**

Pain reliever/Fever reducer

Nasal decongestant

**Uses**

- temporarily relieves symptoms due to the common cold
  - minor aches and pains
  - headache
  - fever
  - nasal congestion
  - sinus congestion & pressure
- temporarily relieves symptoms due to hay fever or other upper respiratory allergies
  - minor aches and pains
  - headache
  - nasal congestion
  - sinus congestion & pressure

**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 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.

**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

**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 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
- you get nervous, dizzy or sleepless

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

**Directions**

- take only as directed
- do not exceed 4 doses per 24 hrs

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

**Other information**

- store at room temperature 15°-30°C (59°-86°F)

**Inactive ingredients**

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink

**Questions or comments?**

Call toll free: **1-855-215-8180**

**PRINCIPAL DISPLAY PANEL - Carton Label**

Daytime Congestion, Pressure & Pain 24 SOFTGELS

NDC 69842-018-04

\*Compare to the active ingredients in Vicks® Sinex™ Daytime Congestion, Pressure & Pain



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

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- if you are now taking a prescription medicine in tablet (M&D) or (certain drugs for depression, psychiatric or emotional conditions, Parkinson's disease), or for 2 weeks after stopping the M&D drug. If you do not know if your prescription drug contains an M&D, ask a doctor or pharmacist before taking this product.

**Drug Facts (continued)**

**Inactive ingredients**

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, polydone, propylene glycol, purified water, sorbitol sorbitan solution and white ink

**Questions or comments? Call toll free: 1-855-2-15-81-80**

This product is not manufactured or distributed by The Procter & Gamble Manufacturing Company, owner of the registered trademarks Vicks® and Sinex™ Daytime Congestion Pressure & Pain.

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<b>DAYTIME CONGESTION PRESSURE AND PAIN</b>			
acetaminophen, phenylephrine hydrochloride capsule, liquid filled			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-018
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
<b>Inactive Ingredients</b>			

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

### Product Characteristics

Color	orange (clear)	Score	no score
Shape	capsule (oblong)	Size	20mm
Flavor		Imprint Code	PC12
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-018-04	2 in 1 CARTON	04/13/2017	
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	04/13/2017	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(69842-018) , analysis(69842-018)

Revised: 11/2019

CVS PHARMACY, INC.