

**ACETAMINOPHEN, GUAIFENESIN, PHENYLEPHRINE HCL AND  
DEXTROMETHORPHAN HBR- acetaminophen, guaifenesin, phenylephrine hcl  
and dextromethorphan hbr capsule, liquid filled  
Softgel Healthcare Pvt Ltd**

-----

**Acetaminophen 325mg, Guaifenesin 200mg, Phenylephrine Hydrochloride  
5mg and Dextromethorphan Hydrobromide 10mg softgelatin Capsules**

***Active ingredients (in each Softgel)***

Acetaminophen USP 325 mg

Dextromethorphan HBr USP 10 mg

Guaifenesin USP 200 mg

Phenylephrine HCl USP 5 mg

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Expectorant

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 passage ways 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 8 softgels in 24 hrs, 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 get worse or last 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.**

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
- do not exceed 8 softgels per 24 hrs

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

**Other information**

- store at no greater than 25 ° C

**Inactive ingredients**

FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

MAX STRENGTH

NDC 35916-0166-1

Compared to the active ingredient in Vicks® DayQuil™ severe COLD & FLU LiquiCaps™

Acetaminophen 325mg, Guaifenesin 200mg, Phenylephrine HCl 5mg And Dextromethorphan HBr 10mg Softgelatin Capsules

Headache, Fever, Sore throat, Minor aches & Pains

Chest congestion, Thins & loosen mucus

Nasal congestion, Sinus Pressure

cough

24 Softgels

Day Time Severe Cold & Flu

(Non-Drowsy)

**Drug Facts**

**Active Ingredients (in each Softgel)**

Acetaminophen USP 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr USP 10 mg.....	Cough suppressant
Guaifenesin USP 200 mg.....	Expectorant
Phenylephrine HCl USP 5 mg.....	Nasal decongestant

**Purpose**

**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 8 Softgels in 24 hrs, 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.

**Drugs Facts (Continued)**

**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  
 ■ now 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 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 ■ do not exceed 8 Softgels per 24 hrs

adults & 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 no greater than 25° C

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

**TAMPER EVIDENT:** This package is safety-sealed. Use only if blisters are intact. If difficult to open, use scissors.

Unvarnished Area  
LH - 83x18 mm

**PARENTS :**  
 Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

Manufactured by:  
 Softgel Healthcare Pvt. Ltd.,  
 Survey No. 20/1, Vandalur-Kelambakkam Road,  
 Pudupakkam Village, Kancheepuram District,  
 Tamilnadu - 603 103, India.

Mfg. Lic. No.: XXXXXXXXXXXX



\*This product is not manufactured or distributed by Procter & Gamble, Owner of the registered trademark Vicks® DayQuil™ severe

**MAX STRENGTH**

NDC 35916-0166-1

Compared to the active ingredient in  
Vicks® DayQuil™ severe COLD & FLU LiquiCaps™

**Acetaminophen 325mg, Guaifenesin 200mg ,  
Phenylephrine HCl 5mg and Dextromethorphan HBr 10mg  
Softgelatin Capsules**

24 Softgels



Day Time Severe Cold & Flu  
(Non - Drowsy)

Acetaminophen 325mg, Guaifenesin 200mg ,  
Phenylephrine HCl 5mg and Dextromethorphan HBr 10mg Softgelatin Capsules

Phenylephrine HCl 5mg and Dextromethorphan HBr 10mg Softgelatin Capsules

Acetaminophen 325mg, Guaifenesin 200mg ,  
Phenylephrine HCl 5mg and Dextromethorphan HBr 10mg Softgelatin Capsules

- Headache, Fever, Sore throat, Minor Aches & Pains
- Chest Congestion, Thins & Loosens Mucus
- Nasal Congestion, Sinus Pressure
- Cough

**ACETAMINOPHEN, GUAIFENESIN, PHENYLEPHRINE HCL AND DEXTROMETHORPHAN HBR**  
 acetaminophen, guaifenesin, phenylephrine hcl and dextromethorphan hbr capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0166
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	

## Product Characteristics

<b>Color</b>	orange (Transparent)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (oblong square)	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0166-1	2 in 1 CARTON	10/29/2024	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	10/29/2024	

