

**ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND PHENYLEPHRINE HYDROCHLORIDE- acetaminophen, dextromethorphan hydrobromide and phenylephrine hydrochloride capsule, liquid filled Softgel Healthcare Pvt Ltd**

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**Acetaminophen 325 mg, Dextromethorphan HBr 10mg and Phenylephrine HCl 5 mg Softgelatin Capsules (Day Time)**

**Active ingredient (in each Softgel)**

Acetaminophen USP 325 mg

Dextromethorphan HBr USP 10 mg

Phenylephrine HCl USP 5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

**Uses**

Temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever

**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, 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**

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

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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

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**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.

<b>Drug Facts</b>	cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
<b>Active Ingredient (in each Softgel)</b>	<b>Purpose</b>
Acetaminophen USP 325 mg.....Pain reliever/fever reducer	Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.
Dextromethorphan HBr USP 10 mg.....Cough suppressant	When using this product, do not use more than directed.
Phenylephrine HCl USP 5 mg.....Nasal decongestant	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.
Uses temporarily relieves common cold/flu symptoms: • nasal congestion • cough due to minor throat & bronchial irritation • sore throat • headache • minor aches & pains • fever	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.
<b>Warnings</b> 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.	<b>Directions</b> • take only as directed • do not exceed 8 Softgels per 24 hrs
<b>Do not use</b> • 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.	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
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	<b>Other information</b> • store at no greater than 25° C
	<b>Inactive ingredients</b> FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution.
	<b>TAMPER EVIDENT:</b> This package is safety-sealed. Use only if blisters are intact. If difficult to open, use scissors.
	*This product is not manufactured or distributed by Procter & Gamble, Owner of the registered trade mark Vicks® Dayquil™ Cold & Flu LiquiCaps

Unvarnished Area  
LH - 83x18 mm

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



Mfg. Lic. No.: XXXXXXXXXXXXX

NDC 35916-0155-1

Compared to the active ingredient in  
Vicks® Dayquil™ Cold & Flu LiquiCaps\*

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

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

- Fever, Sore throat, Headache, Minor aches & pains
- Cough due to minor throat & bronchial irritation
- Nasal congestion



**Day Time**

Cold & Flu (Non - Drowsy)  
48 Softgels

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

# ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, dextromethorphan hydrobromide and phenylephrine hydrochloride capsule, liquid

filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35916-0155
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<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>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

**Inactive Ingredients**

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

**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:35916-0155-1	4 in 1 CARTON	08/15/2024	
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	08/15/2024	

**Labeler** - Softgel Healthcare Pvt Ltd (675584180)

Revised: 8/2024

Softgel Healthcare Pvt Ltd