

**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

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

NDC 35916-0166-1

MAX STRENGTH

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**

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

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

24 Softgels



Day Time Severe Cold & Flu
(Non - Drowsy)

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

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

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

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

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

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

