

**ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate and phenylephrine hydrochloride capsule, liquid filled
SOFTGEL HEALTHCARE PRIVATE LIMITED**

Acetaminophen 325 mg , Dextromethorphan Hydrobromide 10 mg, Doxylamine Succinate 6.25 mg and Phenylephrine Hydrochloride 5 mg (Night Time Severe)

Active ingredients (in each Softgel)

Acetaminophen USP 325 mg

Dextromethorphan Hydrobromide USP 10 mg

Doxylamine succinate USP 6.25 mg

Phenylephrine Hydrochloride USP 5 mg

Purpose

Pain reliever/Fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- Cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages
- temporarily restores free breathing through the nose
- promotes nasal and/or sinus drainage

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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not use more than directed**
- excitability may occur, especially in children

- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, & tranquilizers may increase drowsiness

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.

Keep out of reach of children.

Overdosage

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 Blue No.1, D&C Yellow No.10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water and sorbitol sorbitan solution.

TAMPER EVIDENT

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

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

Drug Facts	Drug Facts (Continued)						
<p>Active ingredient (in each Softgel)</p> <p>Acetaminophen USP 325 mg.....Pain reliever/Fever reducer Dextromethorphan Hydrobromide USP 10 mg.....Cough suppressant Doxylamine succinate USP 6.25 mg.....Antihistamine Phenylephrine Hydrochloride USP 5 mg.....Nasal decongestant</p> <p>Uses temporarily relieves common cold/flu symptoms • nasal congestion • sinus congestion & pressure • cough due to minor throat & bronchial irritation • Cough to help you sleep • minor aches & pains • headache • fever • sore throat • runny nose & sneezing • reduces swelling of nasal passages • temporarily restores freer breathing through the nose • promotes nasal and/or sinus drainage</p> <p>Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take • more than 8 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 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.</p> <p>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.</p> <p>Ask a doctor before use if you have • liver disease • heart disease • high blood pressure • thyroid disease • diabetes • glaucoma • cough that occurs with too much</p>	<p>phlegm (mucus) • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema • trouble urinating due to enlarged prostate gland</p> <p>Ask a doctor or pharmacist before use if you are • taking sedatives or tranquilizers • taking the blood thinning drug warfarin</p> <p>When using this product, do not use more than directed • excitability may occur, especially in children • marked drowsiness may occur • avoid alcoholic drinks • be careful when driving a motor vehicle or operating machinery • alcohol, sedatives, and tranquilizers may increase drowsiness</p> <p>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.</p> <p>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.</p> <p>Directions • take only as directed • do not exceed 8 Softgels per 24 hrs</p> <table border="1"> <tr> <td>adults & children 12 yrs & over</td> <td>2 Softgels with water every 4 hrs</td> </tr> <tr> <td>children 4 to under 12 yrs</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 yrs</td> <td>do not use</td> </tr> </table> <p>Other information • store at no greater than 25° C</p> <p>Inactive ingredients D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water and sorbitol sorbitan solution.</p>	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
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Unvarnished Area
LH - 83x18 mm

TAMPER EVIDENT:

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® Nyquil™ Severe Cold & Flu LiquiCaps™

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 35916-0167-1

*Compared to the active ingredient in Vicks® Nyquil™ Severe Cold & Flu LiquiCaps™

Max Strength

**Acetaminophen 325 mg, Dextromethorphan HBr 10 mg,
Doxylamine Succinate 6.25 mg and Phenylephrine HCl 5 mg
Softgelatin Capsules**

- Fever, Sore throat, Headache, Minor Aches & Pains
- Nasal Congestion, Runny Nose & Sneezing
- Sinus Congestion & pressure
- Cough

Nighttime relief



Night Time Severe
(Cold & Flu - 24 Softgels)

Acetaminophen 325 mg, Dextromethorphan HBr 10 mg,
Doxylamine Succinate 6.25 mg and Phenylephrine HCl 5 mg Softgelatin Capsules

Acetaminophen 325 mg, Dextromethorphan HBr 10 mg,
Doxylamine Succinate 6.25 mg and Phenylephrine HCl 5 mg Softgelatin Capsules

**ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE,
DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE**
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate and phenylephrine

hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0167
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green (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:35916-0167-1	2 in 1 CARTON	08/22/2024	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M012	08/22/2024	

Labeler - SOFTGEL HEALTHCARE PRIVATE LIMITED (676666501)

Revised: 1/2026

SOFTGEL HEALTHCARE PRIVATE LIMITED