

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND DOXYLAMINE SUCCINATE- acetaminophen, dextromethorphan hydrobromide and doxylamine succinate capsule, liquid filled
Softgel Healthcare Private Limited

Acetaminophen 325 mg, Dextromethorphan Hydrobromide 15mg and Doxylamine Succinate 6.25 mg Softgelatin Capsules (Night time)

Active ingredients(in each Softgel)

Acetaminophen USP 325 mg

Dextromethorphan HBr USP 15 mg

Doxylamine succinate USP 6.25 mg

Purpose

Pain reliever/Fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing

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.

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
- 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

- pain 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

adults & children 12 yrs & over	2 softgels with water every 6 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

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, sorbitol sorbitan solution, water

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 - 603103, India
Mfg. Lic. No: xxxxxxxxxxxxxxxx

PRINCIPAL DISPLAY PANEL

NDC Code: 35916-0154-1

*Compared to the active ingredient in VICKS[®] NyQuil[™] Cold & F Liquicaps[™]

Acetaminophen 325 mg, Dextromethorphan Hbr 15 mg and Doxylamine Succinate 6.25 mg Softgelatin Capsules

Fever, Sore Throat, Headache, Minor Aches & Pains

Runny Nose & Sneezing

Cough

Night time

(Cold & Flu - 12 Softgels)

Drug Facts

Active ingredients (in each Softgel)	Purpose
Acetaminophen USP 325 mg	Pain reliever/Fever reducer
Dextromethorphan HBr USP 15 mg	Cough suppressant
Doxylamine succinate USP 6.25 mg	Antihistamine

Uses temporarily relieves common cold/flu symptoms : cough due to minor throat & bronchial irritation ■ sore throat ■ headache ■ minor aches & pains ■ fever ■ runny nose & sneezing

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.

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 ■ 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

Drug Facts (Continued)

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, and tranquilizers may increase drowsiness

Stop use and ask a doctor if ■ pain 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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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

*This product is not manufactured or distributed by Procter & Gamble, Owner of the registered trademarks Vicks® Nyquil™ Cold & Flu Liquicaps™

Manufactured by:
Softgel Healthcare Pvt. Ltd.,
Survey No. 201, Vandalur-Kelambakkam Road,
Pudupakkam Village, Kancheepuram District,
Tamilnadu - 603 103, India.

Mfg. Lic. No.: XXXXXXXXXXXXX



NDC 35916-0154-1

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

Acetaminophen 325 mg, Dextromethorphan HBr - 15 mg
and Doxylamine Succinate 6.25 mg Softgelatin Capsules

Acetaminophen 325 mg, Dextromethorphan HBr 15 mg and Doxylamine Succinate 6.25 mg Softgelatin Capsules

- Fever, Sore throat, Headache, Minor aches & Pains
- Runny Nose & Sneezing
- Cough



Night Time
(Cold & Flu - 12 Softgels)

Acetaminophen 325 mg, Dextromethorphan HBr 15 mg
and Doxylamine Succinate 6.25 mg Softgelatin Capsules

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE AND DOXYLAMINE SUCCINATE

acetaminophen, dextromethorphan hydrobromide and doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-0154
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

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:35916-0154-1	1 in 1 CARTON	09/27/2024	
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	09/27/2024	

