

NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled
Chain Drug Marketing Association, Inc.

QC® QUALITY CHOICE Severe NightTime Cold & Flu

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Purposes

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 freer 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 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to enlarged prostate gland
- 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

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

- 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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take only as directed
- do not exceed 8 softgels per 24 hrs

adults & children	2 softgels with water
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12 yrs & over	every 4 hours
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- store at 20-25°C (68-77°F)
- protect from light, heat and moisture

Inactive ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

Questions?

Call toll free: **1-888-423-0139**

Compare to the active ingredients in Vicks® NyQuil™ Severe Cold & Flu Relief LiquiCaps™*

Temporarily relieves common cold/flu symptoms:

aches, fever and sore throat
controls cough
nasal congestion
runny nose and sneezing

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Procter & Gamble Company, owner of the registered trademarks Vicks®, NyQuil™.

100% QC SATISFACTION GUARANTEED

Distributed by CDMA, Inc.
43157 W Nine Mile
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

Product of India
Packaged and Quality Assured in the USA

Packaging

QC QUALITY CHOICE NDC 63868-469-24

Compare to the active ingredients in Vicks[®] NyQuil[™] Severe Cold & Flu Relief Liquid Caps[™]

Severe NightTime Cold & Flu

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Pain reliever/Fever reducer

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Cough suppressant

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Antihistamine

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Nasal decongestant

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24 softgels

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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QC QUALITY CHOICE

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Nov, MI 48375

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CT68684824
FEV10010202

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www.qualitychoice.com

WARNING: DO NOT USE IF PACKAGING IS DAMAGED OR BLENDED WITH OTHER BRANDS. ANY SIGNS OF TAMPERING.

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Drug Facts (continued)

Uses

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- sinus congestion & pressure
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- heart disease
- diabetes
- high blood pressure
- glaucoma
- liver disease
- thyroid disease

Drug Facts (continued)

- trouble urinating due to enlarged prostate gland
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Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take only as directed
- do not exceed 6 softgels per 24 hrs

adults & children 12 yrs & over	2 softgels with water every 4 hours
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Drug Facts (continued)

Other information

- store at 20-25°C (68-77°F)
- protect from light, heat and moisture

Inactive ingredients: DAC yellow #10, FD&C Blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sodium hydroxide, sodium saccharin solution, titanium dioxide

Questions? Call Toll Free: 1-888-422-9139

LOT: No Varnish

EXP:

6 35515 99884 1

DRUG FACTS TABLE

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Questions? Call toll free: 1-888-423-0139

NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-468
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
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL (oblong)	Size	20mm
Flavor		Imprint Code	789
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-468-24	2 in 1 CARTON	05/03/2022	
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	05/03/2022	

Labeler - Chain Drug Marketing Association, Inc. (011920774)