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

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# QUALITY CHOICE® Maximum Strength NightTime Severe 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

### **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 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 • 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, 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. 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

	2 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor

### Other information

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

# Inactive ingredients

edible printing ink, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, purified water, sorbitol sorbitan solution

### **Ouestions or comments?**

Call **1-888-577-8033** Monday-Friday 8am to 4pm EST.

\*Compare to the Active Ingredients in Vicks® NyQuil™ Severe Cold & Flu Relief LiquiCaps™

# **Maximum Strength**

READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT WARNINGS AND INFORMATION

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

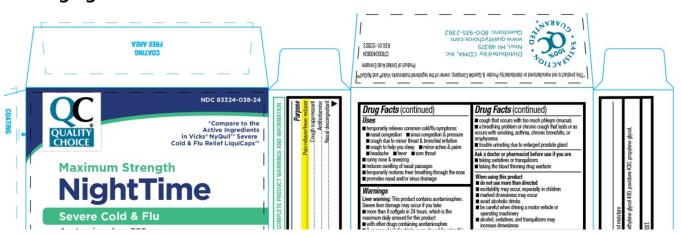
\*This product is not manufactured or distributed by Procter & Gamble Company, owner of the registered trademarks Vicks  $^{\otimes}$  and NyQuil $^{\text{m}}$ .

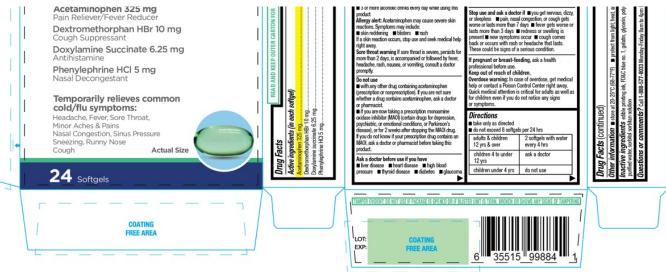
Product of United Arab Emirates

### OC 100% SATISFACTION GUARANTEED

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

# **Packaging**





#### DRUG FACTS LABEL

#### Drug Facts Active ingredients (in each softgel) Purpose Dextromethorphan HBr 10 mg. .Cough suppressant Doxylamine succinate 6.25 mg. Antihistamin Phenylephrine HCl 5 mg.. Nasal decongestan

### **Drug Facts** (continued)

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- 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
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- reduces swelling of nasal passages
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- skin reddening
   blisters
   rash
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#### 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.
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■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ glaucoma

### *Drug Facts* (continued)

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#### Directions

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	•
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

#### Drug Facts (continued)

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

Inactive ingredients edible printing ink, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol 400, povidone K30, propylene glycol, nurified water sorbitol sorbitan solution

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# **QUALITY CHOICE 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:83324-038
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6092ICV9RU)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	812
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324- 038-24	2 in 1 CARTON	01/12/2024	
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	01/12/2024		

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

Revised: 3/2024 Chain Drug Marketing Association, Inc.