

NIGHT TIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled
Major Pharmaceuticals

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose

Pain reliever/Fever Reducer

Cough suppressant

Antihistamine

Uses

- temporarily relieves common cold and flu symptoms:
 - sore throat
 - headache
 - minor aches and pains
 - fever
 - runny nose and sneezing
 - cough due to minor throat and bronchial irritation

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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 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
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

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

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

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.

Overdose warning: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- swallow whole; do not crush, chew, or dissolve
- children under 12 years: do not use

Other information

- store between 15°-30°C (59°-86°F)
- avoid excessive heat

Inactive ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

compare to the active ingredients in Vicks® Nyquil™ Cold & Flu LiquiCaps™†
nighttime

cold and flu relief

acetaminophen 325 mg

pain reliever/fever reducer

dextromethorphan HBr 15 mg,

cough suppressant

doxylamine succinate 6.25 mg

antihistamine

relieves: aches, fever, sore throat, cough, runny nose, and sneezing

alcohol-free

softgels**

(**liquid-filled capsules)

†This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, NyQuil™, and LiquiCaps™ are registered trademark of the Procter & Gamble

Company

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT
INFORMATION.**

Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

Package Label

MAJOR®

NDC 0904-6996-44

compare to the active ingredients in
Vicks® NyQuil™ Cold & Flu LiquiCaps™

nighttime cold & flu relief

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cough suppressant
doxylamine succinate 6.25 mg
antihistamine

relieves: aches, fever, sore throat,
cough, runny nose, and sneezing

16 softgels** (**liquid-filled capsules)

alcohol-free



actual size

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

PLD-G585C
FC009707

Lot No.:
Exp. Date:

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Drug Facts (continued)

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Questions or comments?

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MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268
(800) 616-2471
www.major-rugby.com
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www.StopMedicineAbuse.org

MAJOR Nighttime Cold & Flu Relief

NIGHT TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6996
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	PC10

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6996-44	16 in 1 CARTON	09/30/2019	
1		1 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	09/30/2019	

Labeler - Major Pharmaceuticals (191427277)

Revised: 1/2026

Major Pharmaceuticals