

NIGHT TIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled
FSA Store Inc. (Caring Mills)

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 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 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 that lasts 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
- **when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing**

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 Vicks® NyQuil® Cold & Flu LiquiCaps® active ingredients

Nighttime

Pain Reliever, Fever Reducer,

Cough Suppressant, Antihistamine

Acetaminophen

Dextromethorphan HBr

Doxylamine Succinate

Cold & Flu

Nighttime Relief

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.

Manufactured for **FSA Store Inc.**

5473 BLAIR ROAD

SUITE 100

PMB 24308

DALLAS, TX 75231

Package Label

1/16 X 1/16 BLUE ASSIST PERF
FOR MET POLY CTN
NO INK
NO VARNISH

1/16 X 1/16 BLUE ASSIST PERF
FOR MET POLY CTN
NO INK
NO VARNISH

Drug Facts (continued)

Do not use
■ with any other drug containing acetaminophen (prescription or over-the-counter).
■ if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
■ if you are now taking a prescription narcotic and/or tranquilizer (MAOI) (certain drugs for depression, Parkinson's disease, or anesthesia), 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:
■ blood clotting due to an enlarged prostate gland
■ breathing problem or chronic cough that lasts 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
■ avoid alcohol, driving, and machinery may increase drowsiness
■ avoid driving, alcohol, and machinery may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery

Drug Facts (continued)

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 hives that lasts
■ If pregnant or breast-feeding, ask a health professional before use.
■ Keep out of reach of children.
■ Overdose warnings: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-422-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
■ 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
■ Children under 12 years: Do not use
■ When using other Daytime or Nighttime products, carefully read each label to ensure correct dosing
■ 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, butyl, light mineral oil, mannitol, polyethylene glycol, potassium, propylene glycol, purified water, sodium, stearic, white ink
■ Questions or comments?
■ Call 1-877-452-3835 Monday-Friday 9AM-5PM EST

This product is not manufactured or distributed by The Procter & Gamble Company. Vicks, Nyquil, and Liquicaps are registered trademarks of The Procter & Gamble Company.

Drug Facts (continued)

Warnings
■ Liver warnings: 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
■ 1 or more alcohol drinks every day while using this product

Drug Facts (continued)

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■ Adults and children 12 years and over: Take 2 softgels with water every 6 hours
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Drug Facts (continued)

Do not use
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■ if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
■ if you are now taking a prescription narcotic and/or tranquilizer (MAOI) (certain drugs for depression, Parkinson's disease, or anesthesia), 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.
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16-9985122 NDC



Compare to Vicks® Nyquil® Cold & Flu LiquiCaps® active ingredients

Nighttime

Pain Reliever, Fever Reducer,
Cough Suppressant, Antihistamine

Acetaminophen
Dextromethorphan HBr
Doxylamine succinate

Cold & Flu
Nighttime Relief

16 Softgels*
(*Liquid-filled capsules)



Actual Size

Manufactured for FSA Store Inc.
5473 BLAIR ROAD
SUITE 100
PMB 24308
DALLAS, TX 75231

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org



3 59726 88817 8

CAUTION: EXCESSIVE USE MAY CAUSE LIVER DAMAGE. DO NOT TAKE MORE THAN 4,000 MG OF ACETAMINOPHEN IN 24 HOURS. SEE WARNING FOR COMPLETE WARNINGS AND PRECAUTIONS. KEEP OUT OF REACH OF CHILDREN. P.D.-151533 FOLIOGHE

Lot No.:
Exp. Date:

Nighttime Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine

NIGHT TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81522-899
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)	
MANNITOL (UNII: 3OWL53L36A)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Product Characteristics			
Color	green (clear)	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	PC10
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81522-899-16	16 in 1 CARTON	11/25/2022	
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	11/25/2022	

Labeler - FSA Store Inc. (Caring Mills) (049283340)

Revised: 6/2024

FSA Store Inc. (Caring Mills)