

**NIGHT TIME COLD AND FLU RELIEF MULTI SYMPTOM- acetaminophen,
dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled
Fred's Inc**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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 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 insure correct dosing**

Other information

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

Inactive ingredients

D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol

*may contain this ingredient

Questions or comments?

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

Principal Display Panel

NIGHTTIME MULTI-SYMPTOM

Cold & Flu Relief

325 mg - Acetaminophen (Pain reliever/fever reducer) • Aches, Fever & Sore Throat

15 mg - Dextromethorphan HBr (Cough suppressant) • Cough

6.25 mg - Doxylamine succinate (Antihistamine) • Sneezing, Runny Nose

Alcohol-Free

SOFTGELS**

(**LIQUID-FILLED CAPSULES)

Compare to the Active Ingredients in Vicks® NyQuil® Cold & Flu LiquiCaps®†

†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: fred's, Inc.

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

Questions or comments: 1-855-331-FRED (3733)

Package Label



NDC 55315-471-24

ACTUAL SIZE



NIGHTTIME MULTI-SYMPTOM

Cold & Flu Relief

- 325 mg - Acetaminophen (Pain reliever/Fever Reducer)
- 15 mg - Dextromethorphan HBr (Cough suppressant)
- 6.25 mg - Doxylamine Succinate (Antihistamine)

- Aches, Fever & Sore Throat
- Cough
- Sneezing, Runny Nose

Alcohol-Free

24 SOFTGELS**
(**LIQUID-FILLED CAPSULES)

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i No.:
p. Date:

<p>Drug Facts (continued)</p> <p>Warnings</p> <p>Do not use 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.</p> <p>Ask a doctor before use if you have liver disease or glaucoma. Trouble urinating due to an enlarged prostate gland. A breathing problem or chronic cough that lasts as occurs with smoking, asthma, chronic bronchitis or emphysema. Cough that occurs with too much phlegm (mucus).</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin or taking sedatives or tranquilizers. 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.</p> <p>Drug Facts (continued)</p> <p>Warnings</p> <p>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 redness, rash, 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.</p> <p>Do not use 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.</p> <p>Ask a doctor before use if you have liver disease or glaucoma. Trouble urinating due to an enlarged prostate gland. A breathing problem or chronic cough that lasts as occurs with smoking, asthma, chronic bronchitis or emphysema. Cough that occurs with too much phlegm (mucus).</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin or taking sedatives or tranquilizers. 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.</p> <p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <p>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.</p> <p>When using other Daytime or Nighttime products, carefully read each label to ensure correct dosing.</p> <p>Other information</p> <p>Store between 15-30°C (59-86°F). Avoid excessive heat.</p> <p>Inactive ingredients</p> <p>D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol. May contain this ingredient.</p>
<p>Drug Facts (continued)</p> <p>Directions</p> <p>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.</p> <p>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 right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Uses</p> <p>Temporarily relieves common cold and flu symptoms: minor aches and pains, sore throat, headache, runny nose and sneezing. Cough due to minor throat and bronchial irritation.</p>	<p>Drug Facts</p> <p>Active ingredients (in each softgel)</p> <p>Acetaminophen 325 mg.....Pain reliever/Fever reducer</p> <p>Dextromethorphan HBr 15 mg.....Cough suppressant</p> <p>Doxylamine succinate 6.25 mg.....Antihistamine</p>

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PLD-A41S FC003901

Fred's Pharmacy NightTime Multi-Symptom Cold & Flu Relief

NIGHT TIME COLD AND FLU RELIEF MULTI SYMPTOM

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-471
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)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	P30;94A;SCU1;215;P120
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-471-16	16 in 1 CARTON	10/31/2015	12/30/2021
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:55315-471-24	2 in 1 CARTON	10/31/2015	12/30/2021
2		8 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 FINAL	part341	10/31/2015	12/30/2021

Labeler - Freds Inc (005866116)

Revised: 12/2019

Freds Inc