

NIGHTTIME MULTI SYMPTOM COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled Family Dollar (FAMILY WELLNESS)

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

COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® NYQUIL® COLD & FLU LIQUICAPS®†

Night Time

Multi Symptom

Cold and Flu Relief

Acetaminophen, Dextromethorphan HBr, Doxylamine succinate

For relief of: •Aches, •Fever, •Sore Throat, •Cough, •Sneezing, •Runny Nose

SOFTGELS

LIQUID-FILLED SOFTGELS

**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: MIDWOOD BRANDS, LLC

10611 MONROE RD, MATTHEWS, NC 28105 USA

Package Label

COMPARE TO THE ACTIVE INGREDIENTS IN
VICKS[®] NYQUIL[®] COLD & FLU LIQUICAPS[®]

NDC 55319-771-24

FAMILY
wellness[™]

Nighttime Multi-Symptom Cold & Flu Relief

Acetaminophen, Dextromethorphan HBr,
Doxylamine Succinate

For Relief of:

- Aches • Fever • Sore Throat
- Cough • Sneezing • Runny Nose



OTC



IF OUTER CARTON IS OPENED OR IF BILSTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:
Exp. Date:

Drug Facts (continued)

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

Drug Facts (continued)

Directions
■ do not take more than 4 doses in 24 hours ■ do not take more than 12 years and over; take 2 softgels with water every 6 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, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitan, sorbitol ■ may contain this ingredient

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Drug Facts (continued)

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10611 MONROE RD., MATTHEWS, NC 28105

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



NOT 100% SATISFIED?

Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

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PLD-D41S FC004289

FAMILY WELLNESS Nighttime Multi-Symptom Cold & Flu Relief

NIGHTTIME MULTI SYMPTOM COLD AND FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55319-771 |
| 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: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 15 mg |
| DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (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:55319-771-24 | 16 in 1 CARTON | 08/31/2015 | 04/26/2024 |
| 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 final | part341 | 08/31/2015 | 04/26/2024 |

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 10/2021

Family Dollar (FAMILY WELLNESS)