

NITE TIME COLD MEDICINE- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate liquid
Rij Pharmaceutical Corporation

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 15 mL tablespoon) | Purpose |
|--|-----------------------------|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Dextromethorphan HBr, 15 mg | Cough suppressant |
| Doxylamine succinate 6.25 mg | Antihistamine |

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose and sneezing

Warnings

Liver warning

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

- more than 4 doses 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

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.
- to make a child sleep
- if you are allergic to acetaminophen or any of the ingredients in this product.

Ask a doctor before use if you have

- liver disease
- 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
- a sodium-restricted diet

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

- 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 serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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 recommended - see Overdose warning
- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hrs

| | |
|---------------------------------------|----------------------------|
| Adults and children 12 years and over | 2 TBSP (30 ml) every 6 hrs |
| Children 4 to 12 years | Ask a doctor |
| Children under 4 years | Do not use |

Other information

- store at room temperature 15° - 30°C (59° - 86°F)
- protect from freezing.
- each tablespoon (15 mL) contains: sodium 46 mg

- **TAMPER EVIDENT: DO NOT USE IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING**

Inactive ingredients

alcohol, citric acid, D&C Yellow No. 10, FD&C Green No. 3, FD&C Yellow No. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, saccharin sodium, sodium citrate, sodium benzoate, water

PRINCIPAL DISPLAY PANEL

| | | | | | | | | | | | | | | |
|--|------------------------------|------------------------------|-----------------------------|-------------------|------------------------------|---------------|---|--|---------------------------------------|-----------------------------|------------------------|--------------|------------------------|------------|
| <p>Drug Facts</p> <p>Active Ingredients (in each 15 mL tablespoon)</p> <table border="0"> <tr> <td>Acetaminophen 325 mg</td> <td>Pain Reliever/ Fever Reducer</td> </tr> <tr> <td>Dextromethorphan HBr, 15 mg</td> <td>Cough Suppressant</td> </tr> <tr> <td>Doxylamine Succinate 6.25 mg</td> <td>Antihistamine</td> </tr> </table> <p>Uses temporarily relieves common cold/flu symptoms:</p> <ul style="list-style-type: none"> cough due to minor throat and bronchial irritation sore throat fever headache runny nose and sneezing minor aches & pains <p>Warnings: Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take more than 4 doses in 24 hours, which is the maximum daily amount of this product. With other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product.</p> <p>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 with any other drugs containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</p> <p>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 to make a child sleep. If you are allergic to acetaminophen or any of the ingredients in this product.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> liver disease 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 an enlarged prostate gland a sodium-restricted diet <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> taking sedatives or tranquilizers taking the blood thinning drug warfarin. <p>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.</p> | Acetaminophen 325 mg | Pain Reliever/ Fever Reducer | Dextromethorphan HBr, 15 mg | Cough Suppressant | Doxylamine Succinate 6.25 mg | Antihistamine |  <p>NDC 53807-521-06 CONTAINS ALCOHOL 10%</p> <p>Compare To Active Ingredients Of Vick's NyQuil®</p> <p>Nite-Time Cold Medicine Original Flavor</p> <p>New Formula! Pseudoephedrine Free!</p> <ul style="list-style-type: none"> • Antihistamine • Cough Suppressant/Pain Reliever • Fever Reducer <p>6 FL OZ (177 mL)</p> | <p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p>Overdose warning: Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Directions take only as recommended - see Overdose warning. Use dose cup or tablespoon (TBS). Do not exceed 4 doses per 24 hours.</p> <table border="1"> <tr> <td>Adults and children 12 years and over</td> <td>2 TBS (30 mL) every 6 hours</td> </tr> <tr> <td>Children 4 to 12 years</td> <td>Ask a doctor</td> </tr> <tr> <td>Children under 4 years</td> <td>Do not use</td> </tr> </table> <p>Other information store at room temperature 15°-30°C (59°-86°F). Protect from freezing. Each tablespoon (15 mL) contains sodium 46 mg.</p> <p>TAMPER EVIDENT: DO NOT USE IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING.</p> <p>Inactive ingredients: alcohol, citric acid, D&C Yellow No. 10, FD&C Green No. 3, FD&C Yellow No. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, saccharin sodium, sodium citrate, sodium benzoate, water.</p> <p><small>This product is not manufactured or distributed by, the owner of the registered trademark Vick's NYQUIL®.</small></p> <p>REV. 521-0511</p> <p>RUI PHARMACEUTICAL CORP. 40 Commercial Avenue Middletown, NY 10941</p> <p>N 3 53807-521-06 4</p> | Adults and children 12 years and over | 2 TBS (30 mL) every 6 hours | Children 4 to 12 years | Ask a doctor | Children under 4 years | Do not use |
| Acetaminophen 325 mg | Pain Reliever/ Fever Reducer | | | | | | | | | | | | | |
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NITE TIME COLD MEDICINE

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53807-521 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|------------------|
| Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D) | Acetaminophen | 325 mg in 15 mL |
| Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS) | Dextromethorphan Hydrobromide | 15 mg in 15 mL |
| Doxylamine succinate (UNII: V9B19B5YI2) (Doxylamine - UNII:95QB77JKPL) | Doxylamine succinate | 6.25 mg in 15 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| alcohol (UNII: 3K9958V90M) | |
| citric acid monohydrate (UNII: 2968PHW8QP) | |
| D&C Yellow No. 10 (UNII: 35S5W5USQ3G) | |
| FD&C Green No. 3 (UNII: 3P3ONR601S) | |

| | |
|--|--|
| FD&C Yellow No. 6 (UNII: H77VEI93A8) | |
| high fructose corn syrup (UNII: XY6UN3QB6S) | |
| polyethylene glycols (UNII: 3WJQ0SDW1A) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| water (UNII: 059QF0KO0R) | |
| saccharin sodium (UNII: SB8ZUX40TY) | |
| sodium benzoate (UNII: OJ245FE5EU) | |
| sodium citrate (UNII: 1Q73Q2JULR) | |

| Product Characteristics | | | |
|--------------------------------|--------|---------------------|--|
| Color | GREEN | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|------------------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:53807-521-06 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/16/1999 | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part341 | 03/16/1999 | |

Labeler - Rij Pharmaceutical Corporation (144679156)

| Establishment | | | |
|--------------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| Rij Pharmaceutical Corporation | | 144679156 | manufacture(53807-521) |