NITE TIME COLD MEDICINE CHERRY FLAVOR- 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

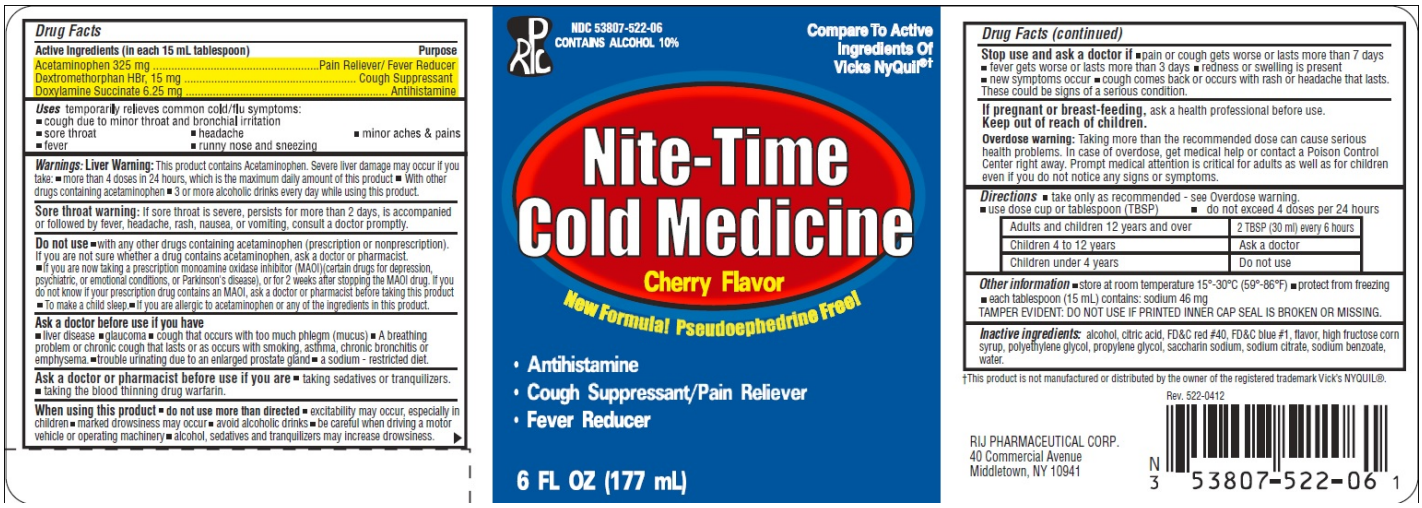
- store at room temperature 15º - 30°C (59º - 86°F)
- protect from freezing.
- each tablespoon (15 mL) contains: sodium 46 mg

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

Inactive ingredients

alcohol, citric acid, FD&C red #40, FD&C blue #1, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, saccharin sodium, sodium citrate, sodium benzoate, water

PRINCIPAL DISPLAY PANEL



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acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53807-522
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: V9BI9B5YI2) (Doxylamine - UNII:95QB77JKPL)	Doxylamine succinate	6.25 mg in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
alcohol (UNII: 3K9958V90M)	
citric acid monohydrate (UNII: 2968PHW8QP)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
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:53807-522-06	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(53807-522)

Revised: 4/2018 Rij Pharmaceutical Corporation