

REVASOL NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr and doxylamine succinate liquid
Rnv LLC

REVASOL NIGHTTIME COLD&FLU

Active ingredients (in each 30 mL dose cup) Purpose

Acetaminophen 650 mg.....Pain Reliever-Fever Reducer
Dextromethorphan HBr 30 mg.....Cough Suppressant
Doxylamine Succinate 12.5mg.....Antihistamine

Pain Reliever-Fever Reducer

Cough Suppressant

Antihistamine

Uses

• temporarily relieves common cold/flu symptoms: • sore throat • minor aches and pains • runny nose and sneezing • headache • fever • cough due to minor throat and bronchial irritation.

Warnings

Liver warning This product contains acetaminophen. Severe liver damage may occur if:

• adults and children over 12 years of age take more than 4 doses (30 mL each in 24 hours,

which is the maximum daily amount for this product

• taken with other drugs containing acetaminophen

• adult has 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, lasts 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

sleepy

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 occur with smoking, asthma, chronic bronchitis or emphysema • trouble urinating due to an enlarged prostate gland.

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

When using this product • do not use more than directed • avoid alcoholic drinks • excitability may occur, especially in children • marked drowsiness may occur • 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.

Keep out of the reach of children. If pregnant or breast-feeding, ask a health professional before use.

Overdose warning:

Taking more than the recommended dose (overdose) could cause serious health problems, including liver damage. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Quick 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 directed (see overdose warning)
- measure only with dosing cup provided and keep dosage cup with product
- mL=milliliter • do not exceed 4 doses per 24 hours

Age	Dose
adults and children 12 years of and over	30 mL every 6 hours
children under 12 years	do not use

- when using Day Time and Night Time products, limit total to 4 doses per 24 hours

Other Information

- **Each 30 mL dose cup contains:** sodium 10 mg
- store at room temperature 15-30°C (59-86°F) and do not refrigerate

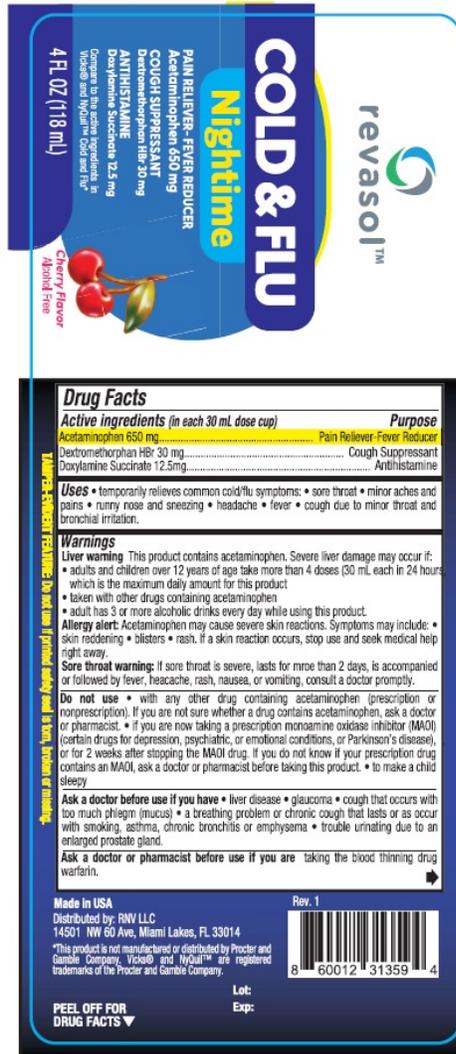
TAMPER-EVIDENT FEATURE: Do not use if printed safety seal is torn, broken or missing.

Inactive ingredients citric acid, FD&C Blue #1, FD&C Red #40, flavor, glycerin,

menthol, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum.

Questions or comments 1-888-446-4753

Monday - Friday (9 AM - 5 PM EST)



Drug Facts (continued)

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Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

Made in USA
 Distributed by: RNW LLC
 14501 NW 60 Ave, Miami Lakes, FL 33014

Rev. 1

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Lot: _____
 Exp: _____

PEEL OFF FOR DRUG FACTS

REVASOL NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr and doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84379-276
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE -	DOXYLAMINE SUCCINATE	12.5 mg

UNII:95QB77JKPL)

DOXYLAMINE SUCCINATE

in 30 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MENTHOL (UNII: L7T10EIP3A)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITOL SOLUTION 70% (UNII: 8KW3E207O2)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84379-276-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/03/2025	

Labeler - Rnv LLC (118917568)**Registrant** - Rnv LLC (118917568)**Establishment**

Name	Address	ID/FEI	Business Operations
Rnv LLC		118917568	manufacture(84379-276)