

XL-3 NIGHT TIME- acetaminophen, dextromethorphan hbr, doxylamine succinate liquid
Rnv LLC

XL-3 Night Time

Active ingredients

(in each 30mL dose cup)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine Succinate 12.5 mg

Pain reliever/fever reducer

Cough Suppressant

Antihistamine

Uses

temporarily relieves cold/flu symptoms:

- sore throat
- headache
- minor aches and pain
- 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 every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than two days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly

Do not use

with any other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's diseases), or for 2 weeks after stopping the MAOI drugs. 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

- a sodium restricted diet
- 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

Ask a doctor or pharmacist before use

- if you are taking sedatives or tranquilizers
- 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

- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, 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 (overdose) may cause serious health problems including liver damage. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

- take only as recommended- see Overdose warning
- use only dosing cup provided
- keep dosing cup provided with the product
- do not exceed 4 doses per 24 hours

- if taking Day Time during the day and Night Time at night, limit the total to 4 doses per 24 hours
- TBSP=tablespoon
- mL=milliliter

adults & children 12 years and over	30 mL (2 TBSP) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

Other information

- each 30 mL contains: **sodium 10 mg**
- store between 58° - 86°F (15°-30° degrees C)

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 from 8 AM - 5 PM Eastern Standard Time

XL-3*

Cherry Flavor
Night Time Xtreme

Multi-Symptom Cold/Flu Relief

Cold and Cough

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Doxylamine succinate - Antihistamine

Fast relief of:

-  SNEEZING & RUNNY NOSE
-  FEVER
-  ACHEs & PAINs
-  COUGH
-  SORE THROAT



12 FL OZ (354 mL)

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-  SORE THROAT



12 FL OZ (354 mL)

XL-3* Xtreme

Cold and Cough

DO NOT USE IF PRINTED SHRINK BAND IS MISSING OR BROKEN

Failure to follow these warnings could result in serious consequences

Drug Facts

Active ingredients (in each 30 mL dose cup)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine Succinate 12.5 mg	Antihistamine

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

DRUG FACTS CONTINUED ON BACK



Distributed by:
Midway Importing, Inc.
1807 Britton Road,
Houston, TX 77043 1-800-531-3873
Made in USA

Rev.1

LR-060 REV 03

Peel back

XL-3* Xtreme Cold and Cough

Drug Facts (continued)

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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

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Sore throat warning: If sore throat is severe, persists for more than two days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use • with any other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist • for more than 10 days for pain unless directed by a doctor • for more than 3 days for fever unless directed by a doctor • 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 drugs. 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

• a sodium restricted diet • 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.

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

Drug Facts (continued)

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 • redness or swelling is present • symptoms do not get better within 7 days or are accompanied by a fever • fever gets worse or lasts more than 3 days • new symptoms occur • cough lasts more than 7 days, comes back, or occurs with fever, 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.**

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Directions • take only as recommended - see Overdose warning • use only dosing cup provided • keep dosing cup provided with the product • do not exceed 4 doses per 24 hours • if taking Night Time at night and Day Time during the day, limit total to 4 doses per 24 hours • TBSP=tablespoon • mL=milliliter

adults & children 12 years and over	30 mL (2 TBSP) every 6 hours
children 4 to under 12 years	ask a doctor
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Other information • each 30 mL contains: sodium 10 mg • store between 58°- 86°F (15°- 30°C).

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.

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XL-3 Xtreme**Cold and Cough**DO NOT USE IF PRINTED SHRINK BAND IS MISSING OR BROKEN
Failure to follow these warnings could result in serious consequences**Drug Facts**

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DRUG FACTS CONTINUED ON BACK

XL-3***Cherry Flavor
Night Time Xtreme**

Multi-Symptom Cold/Flu Relief

Cold and Cough

- Acetaminophen - Pain Reliever/Fever Reducer
- Dextromethorphan HBr - Cough Suppressant
- Doxylamine succinate - Antihistamine

Fast relief of:

- SNEEZING & RUNNY NOSE
- COUGH
- FEVER
- SORE THROAT
- ACHES & PAINS

6 FL OZ (177 mL)

XL-3 Xtreme**Cold and Cough**

LR-116

Rev.1

Distributed by:
Midway Importing, Inc.
1807 Britton Road,
Houston, TX
Made in USA

*Trademark

Pat back

XL-3 Xtreme**Cold and Cough****Drug Facts (continued)**

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XL-3 NIGHT TIME

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84379-444
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
MENTHOL (UNII: L7T10EIP3A)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84379-444-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2024	
2	NDC:84379-444-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/01/2024	

Labeler - Rnv LLC (118917568)

Establishment

Name	Address	ID/FEI	Business Operations
Rnv LLC		118917568	manufacture(84379-444)

Revised: 1/2026

Rnv LLC