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

Acetaminophen 325 mg

Dextromethorphan HBr 10 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 pains
- fever
- runny nose and sneezing
- cough due to minor throat and bronchial irritation

Warnings

Liver warning: This product contains acetaminophen. Sever 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 sever 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 sever, 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 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 diseas), 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 wtih 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
- rever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs wih 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 problemas including liver damamge. 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 ou 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=mililiter

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 degrees 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 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**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	350 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL

DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

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

Packaging

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

Revised: 12/2024 Rnv LLC