# NIGHTTIME COLD AND FLU- acetaminophen, doxylamine succinate and dextromethorphan hbr liquid BI-MART

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#### **NIGHTTIME COLD & FLU**

#### **Drug Facts**

#### Active ingredients (in each 30 mL dose cup)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine Succinate 12.5 mg

#### **Purpose**

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 mroe than 2 days, is accompanied or followed by fever, heacache, 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.
- if you have ever had an allergic reaction to this product or anay of its ingredients

#### 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 sedatives or tranquilizers
- taking the blood thinning drug warfarin.

### When using this product

- do not use more than directed (see overdose warning)
- 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.

#### If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the reach of children.

#### Overdose warning:

Taking mroe 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 (1-800-222-1222) 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=mililiter
- do not exceed 4 doses per 24 hours

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

#### 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

#### Inactive ingredients

citric acid, D&C Yellow #10, FD&C Green #3, FD&C Yellow #6, flavor, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum.

#### Questions or comments?

#### 1-844-912-4012





## **NIGHTTIME**

#### COLD & FLU

Acetaminophen (Pain reliever/fever reducer) Doxylamine Succinate (Antihistamine) Dextromethorphan HBr (Cough suppressant)

Headache, Fever, Sore Throat, Minor Aches & Pains, Sneezing, Runny Nose, Cough

Ages 12 Years and Over

12 FL OZ (355 mL)

#### Drug Facts Active ingredients (in each 30 mL dose cup) Purpose

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

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Liver varianting: This product contains acetaminophen, Severe liver damage way order.
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Adult has 3 on one dischoold drink every of yarihbu using this product.
Adult has 3 one medical had pring this every. All 18 alth nexton cours, some office when death and pring this every. But it is alth nexton cours, some threat warnings if sore throat is every, lasts for more than 2 days, is accompanied or followed by freet, headstore, each, nauses, or vomitting, consult and doctor promptly.
Den of use ever than or worther droug containing acetaminophen increadation acetaminophen increasition or

of its impresients.

Ask a doctor before use if you have \* Iver disease \* glaucoma \* couch that occurs with too much priegm (mucus) \* a breathing problem or chronic cough that lasts or as occur with snoking, asthma, chronic broaders or emptysema \* trouble urinating due to an entarged prostate gland \*

DRUG FACTS CONTENUED ON THE BACK

#### Drug Facts (continued)

writer a review (CONTRIBUEU)

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When using this product \* On on time more than directed dren overdown arming \* and obtained dren's excludely your occur, aspecially in different extensive states of the contribution of the co

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headanche mit lasts. These could be signs of a serious condition. If pregnant or breacheding, sich hold professoral before use, Keep out of the reach of children. Verwicks warming. Thing more than the recommended dose (eventices) could cause sertous health problems, including laver damage, its case of accordance cause works in the problems. Another the camage, its case of accordance recorded, seek professoral assistance or control at Possion Control (14-00-22-27.22) immediately, founds medical distation is ortical for adults are well as for follation early good out offices and agriculture or action for another than the control of the

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Other Information • Each 30 ml. dose cup contains: sodium 10 mg
• store at moon temperature 15-30°C (59-86°F) and do not refrigerate

Inactive ingredients citric acid, D&C Yellow #10, FD&C Green #3, FD& Yellow #6, flavor, glycorin, menthol, propylene glycol, purified water, sodiul benzoate, sorbitol solution, sucralose, xanthan gum.

Questions or comments? 1-844-912-4012

#### NIGHTTIME COLD AND FLU

acetaminophen, doxylamine succinate and dextromethorphan hbr liquid

#### **Product Information Product Type HUMAN OTC DRUG** Item Code (Source) NDC:37835-525 **Route of Administration** ORAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
XANTHAN GUM (UNII: TTV12P4NEE)				
GLYCERIN (UNII: PDC6A3C0OX)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
WATER (UNII: 059QF0KO0R)				
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
MENTHOL (UNII: L7T10EIP3A)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
SORBITOL SOLUTION 70% (UNII: 8KW3E207O2)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				

Product Characteristics			
Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:37835-525- 12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/01/2025	

# **Labeler -** BI-MART (027630078)

### Registrant - BI-MART (027630078)

Establishment			
Name	Address	ID/FEI	Business Operations
Rnv LLC		118917568	manufacture(37835-525)

Revised: 5/2025 BI-MART