

**NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan, doxylamine succinate liquid**

**NIGHTTIME COLD AND FLU LIQUID CHERRY- acetaminophen, dextromethorphan, doxylamine succinate liquid**  
**Grimann, S.A. de C.V.**

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take only as directed

only use the dose cup provided  
do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over

30 mL every 6 hrs

children 4 to under 12 yrs

ask a doctor

children under 4 yrs

do not use

Warnings

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

more than 4 doses in 24 hrs, 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

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, persist for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Inactive ingredients alcohol, citric acid, D&C Yellow No. 10, FD&C Blue No.1, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol, sucralose

Directions

take only as directed

only use the dose cup provided  
do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over

30 mL every 6 hrs

children 4 to under 12 yrs

ask a doctor

children under 4 yrs

do not use

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

Uses

temporarily relieves common cold/flu symptoms:

cough due to minor throat & bronchial irritation

sore throat

headache

minor aches & pains

fever

runny nose and sneezing

Active Ingredients (in each 30 mL) Purpose

Acetaminophen 650

mg.....  
..... Pain reliever/fever reducer

Dextromethorphan HBr 30

mg.....  
..... Cough suppressant

Doxylamine succinate 12.5

mg.....  
..... Antihistamine

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Drug Facts	Purpose
<b>Drug Facts</b> Active ingredients (in each 12 fl oz): Acetaminophen 400 mg Chlorpheniramine HCl 2 mg Dextromethorphan HBr 15 mg Pseudoephedrine HCl 30 mg	<b>Purpose</b> High strength acetaminophen Antihistamine Cough suppressant Decongestant
<b>Uses</b> Relieves or reduces common cold, flu, headache, fever, sore throat, minor aches and pains, sinus pressure, nasal congestion, and cough.	
<b>Warnings</b> Do not use if you are allergic to any of the ingredients listed on the label. Do not use if you are taking any other prescription or over-the-counter drugs that contain acetaminophen, chlorpheniramine, dextromethorphan, or pseudoephedrine. Do not use if you are taking any other prescription or over-the-counter drugs that contain acetaminophen, chlorpheniramine, dextromethorphan, or pseudoephedrine. Do not use if you are taking any other prescription or over-the-counter drugs that contain acetaminophen, chlorpheniramine, dextromethorphan, or pseudoephedrine. Do not use if you are taking any other prescription or over-the-counter drugs that contain acetaminophen, chlorpheniramine, dextromethorphan, or pseudoephedrine.	
<b>Directions</b> See the label for complete directions. Do not use if you are allergic to any of the ingredients listed on the label. Do not use if you are taking any other prescription or over-the-counter drugs that contain acetaminophen, chlorpheniramine, dextromethorphan, or pseudoephedrine. Do not use if you are taking any other prescription or over-the-counter drugs that contain acetaminophen, chlorpheniramine, dextromethorphan, or pseudoephedrine. Do not use if you are taking any other prescription or over-the-counter drugs that contain acetaminophen, chlorpheniramine, dextromethorphan, or pseudoephedrine.	
<b>Other information</b> Keep out of reach of children. Do not use if you are allergic to any of the ingredients listed on the label. Do not use if you are taking any other prescription or over-the-counter drugs that contain acetaminophen, chlorpheniramine, dextromethorphan, or pseudoephedrine. Do not use if you are taking any other prescription or over-the-counter drugs that contain acetaminophen, chlorpheniramine, dextromethorphan, or pseudoephedrine.	

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# NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81660-777

<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
	<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	
	<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	<b>WATER</b> (UNII: 059QF0KO0R)	1 mg in 30 mL		
	<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	1 mg in 30 mL		
	<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	1 mg in 30 mL		
	<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	1 mg in 30 mL		
	<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	1 mg in 30 mL		
	<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	1 mg in 30 mL		
	<b>ALCOHOL</b> (UNII: 3K9958V90M)	1 mg in 30 mL		
	<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	1 mg in 30 mL		
	<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1 mg in 30 mL		
	<b>SORBITOL</b> (UNII: 506T60A25R)	1 mg in 30 mL		
	<b>CITRIC ACID ACETATE</b> (UNII: DS012WL7AU)	1 mg in 30 mL		
	<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	1 mg in 30 mL		
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:81660-777-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/11/2023	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC Monograph Drug	M012	04/11/2023		

<b>NIGHTTIME COLD AND FLU LIQUID CHERRY</b>			
acetaminophen, dextromethorphan, doxylamine succinate liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81660-555
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	1 mg in 30 mL
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<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	1 mg in 30 mL
<b>ALCOHOL</b> (UNII: 3K9958V90M)	1 mg in 30 mL
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	1 mg in 30 mL
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	1 mg in 30 mL
<b>SORBITOL</b> (UNII: 506T60A25R)	1 mg in 30 mL
<b>CITRIC ACID ACETATE</b> (UNII: DS012WL7AU)	1 mg in 30 mL
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	1 mg in 30 mL
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	1 mg in 30 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81660-555-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/11/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/11/2023	

**Labeler** - Grimann, S.A. de C.V. (812806982)

### Establishment

Name	Address	ID/FEI	Business Operations
Grimann, S.A. de C.V.		812806982	manufacture(81660-777, 81660-555) , label(81660-777, 81660-555)

Revised: 1/2026

Grimann, S.A. de C.V.