

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.

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

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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

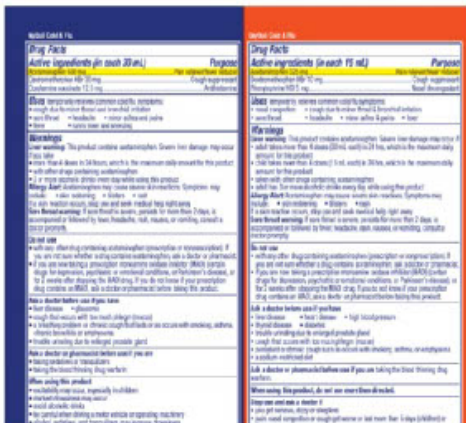
mg.....
..... Antihistamine

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<p>Acetaminophen <i>paracetamol</i> HD, <i>acetaminophen</i> HD</p>	<p>Acetaminophen <i>paracetamol</i> <i>Succinate</i>, <i>Dextromethorphan</i> HD</p>	<p>How to use and how often to use</p> <ul style="list-style-type: none"> • Do not use for more than 10 days, unless told to do so by your doctor • Do not give more than 660 mg per day to children • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Warnings</p> <ul style="list-style-type: none"> • Do not use for more than 10 days unless told to do so by your doctor • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Other information</p> <ul style="list-style-type: none"> • Each bottle contains 120 mL (4 fl. oz.) of liquid • Each bottle contains 120 mL (4 fl. oz.) of liquid <p>Directions</p> <ul style="list-style-type: none"> • Take 1 tablet 4 times a day, with or without food • Take 1 tablet 4 times a day, with or without food <p>Caution</p> <ul style="list-style-type: none"> • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Other information</p> <ul style="list-style-type: none"> • Each bottle contains 120 mL (4 fl. oz.) of liquid • Each bottle contains 120 mL (4 fl. oz.) of liquid 	<p>How to use and how often to use</p> <ul style="list-style-type: none"> • Do not use for more than 10 days, unless told to do so by your doctor • Do not give more than 660 mg per day to children • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Warnings</p> <ul style="list-style-type: none"> • Do not use for more than 10 days unless told to do so by your doctor • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Other information</p> <ul style="list-style-type: none"> • Each bottle contains 120 mL (4 fl. oz.) of liquid • Each bottle contains 120 mL (4 fl. oz.) of liquid <p>Directions</p> <ul style="list-style-type: none"> • Take 1 tablet 4 times a day, with or without food • Take 1 tablet 4 times a day, with or without food <p>Caution</p> <ul style="list-style-type: none"> • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Other information</p> <ul style="list-style-type: none"> • Each bottle contains 120 mL (4 fl. oz.) of liquid • Each bottle contains 120 mL (4 fl. oz.) of liquid
<p>Headache, Fever, Sore Throat, Minor Aches & Pains</p> <p>Nasal Congestion, Sinus Pressure</p> <p>Cough</p> <p><i>Non-Drowsy</i> <i>Alcohol Free</i></p>	<p>Headache, Fever, Sore Throat, Minor Aches & Pains</p> <p>Sneezing, Runny Nose</p> <p>Cough</p> <p><i>Nighttime Relief</i> <i>Alcohol 10%</i></p>	<p>How to use and how often to use</p> <ul style="list-style-type: none"> • Do not use for more than 10 days, unless told to do so by your doctor • Do not give more than 660 mg per day to children • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Warnings</p> <ul style="list-style-type: none"> • Do not use for more than 10 days unless told to do so by your doctor • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Other information</p> <ul style="list-style-type: none"> • Each bottle contains 120 mL (4 fl. oz.) of liquid • Each bottle contains 120 mL (4 fl. oz.) of liquid <p>Directions</p> <ul style="list-style-type: none"> • Take 1 tablet 4 times a day, with or without food • Take 1 tablet 4 times a day, with or without food <p>Caution</p> <ul style="list-style-type: none"> • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Other information</p> <ul style="list-style-type: none"> • Each bottle contains 120 mL (4 fl. oz.) of liquid • Each bottle contains 120 mL (4 fl. oz.) of liquid 	<p>How to use and how often to use</p> <ul style="list-style-type: none"> • Do not use for more than 10 days, unless told to do so by your doctor • Do not give more than 660 mg per day to children • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Warnings</p> <ul style="list-style-type: none"> • Do not use for more than 10 days unless told to do so by your doctor • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Other information</p> <ul style="list-style-type: none"> • Each bottle contains 120 mL (4 fl. oz.) of liquid • Each bottle contains 120 mL (4 fl. oz.) of liquid <p>Directions</p> <ul style="list-style-type: none"> • Take 1 tablet 4 times a day, with or without food • Take 1 tablet 4 times a day, with or without food <p>Caution</p> <ul style="list-style-type: none"> • Do not use if you are allergic to acetaminophen • Do not use if you are allergic to dextromethorphan • Do not use if you are allergic to any of the ingredients <p>Other information</p> <ul style="list-style-type: none"> • Each bottle contains 120 mL (4 fl. oz.) of liquid • Each bottle contains 120 mL (4 fl. oz.) of liquid
<p>2 BOTTLES - 1 DAYQUIL/1 NYQUIL 12 FL. OZ. (354 mL) EACH; TOTAL 24 FL. OZ. (708 mL)</p>			



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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

Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	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	
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0KO0R)	1 mg in 30 mL		
	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	1 mg in 30 mL		
	SODIUM BENZOATE (UNII: OJ245FE5EU)	1 mg in 30 mL		
	SODIUM CITRATE (UNII: 1Q73Q2JULR)	1 mg in 30 mL		
	SUCRALOSE (UNII: 96K6UQ3ZD4)	1 mg in 30 mL		
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mg in 30 mL		
	ALCOHOL (UNII: 3K9958V90M)	1 mg in 30 mL		
	D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	1 mg in 30 mL		
	GLYCERIN (UNII: PDC6A3C0OX)	1 mg in 30 mL		
	SORBITOL (UNII: 506T60A25R)	1 mg in 30 mL		
	CITRIC ACID ACETATE (UNII: DS012WL7AU)	1 mg in 30 mL		
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	1 mg in 30 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81660-777-01	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		

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

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
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	1 mg in 30 mL
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	1 mg in 30 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	1 mg in 30 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR)	1 mg in 30 mL
SUCRALOSE (UNII: 96K6UQ3ZD4)	1 mg in 30 mL
ALCOHOL (UNII: 3K9958V90M)	1 mg in 30 mL
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	1 mg in 30 mL
GLYCERIN (UNII: PDC6A3C00X)	1 mg in 30 mL
SORBITOL (UNII: 506T60A25R)	1 mg in 30 mL
CITRIC ACID ACETATE (UNII: DS012WL7AU)	1 mg in 30 mL
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	1 mg in 30 mL
PROPYLENE GLYCOL (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: 2/2024

Grimann, S.A. de C.V.