AXIM NIGHT TIME - LIQUID- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid
VIVUNT PHARMA LLC

AXIM Night Time Cold & Flu - Liquid

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 common cold/flu symptoms:

- sore throat
- minor aches & pains
- runny nose & sneezing
- headache
- fever
- cough due to minor throat & 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 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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 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 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 any of its ingredients
- to make a child sleep

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 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
- taking the blood thinning drug warfarin

When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- 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.

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Keep out of reach of children.

If pregnant or breast-feeding

ask a health professional before use.

Overdose warning

Taking more than the recommended dose (overdose) could cause serious health

problems, including liver damage. 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

Directions

- take only as directed (see overdose warning)
- measure only with dosage cup provided and keep dosage cup with product
- mL = milliliter
- do not exceed 4 doses per 24 hours
- when using DayTime and NightTime products, limit total to 4 doses per 24 hours

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 - 89°F) and do not refrigerate
- Tamper evident: Do not use if shrink band is missing or broken

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

Distributed by:

VIVUNT PHARMA LLC
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Miami, FL 33156-3178

Made in USA

www.vivunt.live

PRINCIPAL DISPLAY PANEL

Compare to VICKS ®NyQuil ®

Cold & Flu active ingredients*

NDC 82706-012-01

AXIM - NightTime

COLD&FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer

- Cough Suppresant
- Antihistamine

Nighttime Relief

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

12 FL OZ (355 mL)

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AXIM NIGHT TIME - LIQUID

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82706-012
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 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 MONOHYDRATE (UNII: 2968PHW8QP)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-012-01	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/05/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/05/2024	

Labeler - VIVUNT PHARMA LLC (045829437)

Revised: 1/2024 VIVUNT PHARMA LLC