

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

AXIV 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.

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
8950 SW 74th. Court. Suite 1901

Miami, FL 33156-3178

Made in USA

www.vivunt.live

PRINCIPAL DISPLAY PANEL

Compare to VICKS[®] NyQuil[®]

Cold & Flu active ingredients*

NDC 82706-023-01

AXIV - 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)

*This product is not manufactured or distributed by The Procter &Gamble Company, owner of registered trademarks Vicks® NyQuil®

Compare to Vicks® NyQuil® Cold & Flu active ingredients* NDC 82706-023-01

axiv

NightTime
COLD & FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
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NIGHTTIME RELIEF
Acetaminophen
Dextromethorphan HBr
Doxylamine Succinate

CHERRY FLAVOR
ALCOHOL FREE

12 FL OZ (355 mL)

Drug Facts

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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 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 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 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. to make a child sleepy.

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, 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.

Drug Facts (continued)

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.

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 accidental overdose, seek professional assistance or contact a Poison Control Center 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 dosage cup provided and keep dosage cup with product, mL= milliliter, do not exceed 4 doses per 24 hours.

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

when using DayTime and NightTime products, limit total to 4 doses per 24 hours.

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, 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.

VIVUNT™ 30 YEARS

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AXIV NIGHT TIME - LIQUID

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82706-023
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: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (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:82706-023-01	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/14/2024	

Labeler - VIVUNT PHARMA LLC (045829437)

Revised: 5/2024

VIVUNT PHARMA LLC