

AXIV DAYTIME - LIQUID- acetaminophen, dextromethorphan hydrobromide liquid
VIVUNT PHARMA LLC

AXIV - DayTime Cold & Flu - Liquid

Drug Facts

Active ingredients (in each 30 mL dose cup)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant

Uses

Temporarily relieves common cold/flu symptoms:

- minor aches and pains
- headache
- sore throat
- fever
- cough due to minor throat and bronchial irritation

Warnings

Liver warning

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

- 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 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

Ask a doctor before use if you have

- liver disease
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product

do not use more than directed (see overdose warning)

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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 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

- when using DayTime and NightTime products, carefully read each label to ensure correct dosing

adults and children 12 years and over	30 mL every 4 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
- Tamper evident: Do not use if shrink band is missing or broken

Inactive ingredients

Citric acid, FD&C Yellow #6, 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® DayQuil®

Cold&Flu active ingredients*

NDC 82706-022-01

AXIV - DayTime

COLD&FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Nasal Decongestant

Non-Drowsy

Acetaminophen, Dextromethorphan HBr

12 FL OZ (355 mL)

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

Compare to Vicks® DayQuil®
HBP Cold & Flu active ingredients*
NDC 82706-022-01

DayTime

COLD & FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
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NON-DROWSY
Acetaminophen
Dextromethorphan HBr
ALCOHOL FREE

12 FL OZ (355 mL)

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 Acetaminophen 650 mg Pain Reliever-Fever Reducer
 Dextromethorphan HBr 20 mg Cough Suppressant

Uses Temporarily relieves common cold/flu symptoms: ■ minor aches and pains
 ■ headache ■ sore throat ■ 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 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.

Ask a doctor before use if you have ■ liver disease ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough as occurs with smoking, asthma or emphysema.

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

When using this product ■ do not use more than directed (see overdose warning).

Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ pain, nasal congestion or cough get worse or lasts more than 5 days (children) or 7 days (adults) ■ 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.

Drug Facts (continued)

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 4 hours
 children under 12 years do not use
 ■ when using DayTime and NightTime products, carefully read each label to ensure correct dosing.

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 Yellow #6, flavor, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum.

VIVUNT™

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*This product is not manufactured or distributed by Procter & Gamble distributor of Vicks® DayQuil® HBP Cold & Flu.
Rev. 2

AXIV DAYTIME - LIQUID

acetaminophen, dextromethorphan hydrobromide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82706-022
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	20 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-022-01	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)

Establishment

Name	Address	ID/FEI	Business Operations
Rnv LLC		118917568	manufacture(82706-022)

Revised: 5/2024

VIVUNT PHARMA LLC