

**AXIV NIGHTTIME- acetaminophen, dextromethorphan hydrobromide,
doxylamine succinate capsule, liquid filled
VIVUNT PHARMA LLC**

AXIV NightTime Cold & Flu

Drug Facts

<i>Active ingredients (in each softgel)</i>	<i>Purpose</i>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses

Temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing

Warnings

Liver warning

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

- more than 8 Softgels 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 the blood thinning drug warfarin
- taking sedatives or tranquilizers

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 the reach of children

Keep out of reach of children.

If pregnant or breast-feeding

ask a health professional before use.

Overdose warning

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)
- Do not take more than 8 Softgels in 24 hours

adults & children 12 years and over	2 Softgels with water every 6 hrs
children 4 to under 12 years	consult a doctor
children under 4 years	do not use

Other information

- Store at 20° - 25 °C (68 °- 77 °F)
- Read all product information before using
- Tamper Evident: Do not use if the foil printed on the blister is torn or ripped.
- Tamper Evident: Do not use if carton or pouch is open

Inactive ingredients

D&C Yellow No. 10, FD&C Blue No. 1, Gelatin, Glycerin, Methylparaben, Polyethylene Glycol 400, Povidone K30, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Titanium Dioxide

Distributed by:

VIVUNT PHARMA LLC
8950 SW 74th. Court. Suite 1901
Miami, Florida, 33156-3178

Made in India

www.vivunt.live

PRINCIPAL DISPLAY PANEL 24

Compare to VICKS[®] NyQuil[®]

Cold & Flu LiquiCaps[®]

active ingredients*

NDC 82706-016-01

AXIV NightTime Cold & Flu

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer

- Cough Suppressant
- Antihistamine

Nighttime Relief

Acetaminophen, Doxylamine Succinate, Dextromethorphan HBr

24 LiquiCaps** **Liquid-filled capsules



PRINCIPAL DISPLAY PANEL 4 SOFTGELS

Compare to VICKS® NyQuil®

Cold & Flu LiquiCaps®

active ingredients*

NDC 82706-016-02

AXIV NightTime Cold & Flu

Multi-Symptom Relief

Nighttime Relief

Acetaminophen, Doxylamine Succinate , Dextromethorphan HBr

4 LiquiCaps** **Liquid-filled capsules



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

Drug Facts

Active ingredients (in each softgel)
 Acetaminophen 325 mg Pain Reliever/Fever Reducer
 Dextromethorphan Hbr 15 mg Cough Suppressant
 Doxylamine succinate 6.25 mg Antihistamine

Uses Temporarily relieves common cold/flu symptoms: ■ cough due to minor throat and bronchial irritation ■ sore throat ■ headache ■ minor aches and pains ■ fever ■ runny nose and sneezing.

Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 8 Softgels 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 ■ 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 an enlarged prostate gland.

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

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:** 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) ■ do not take more than 8 softgels in 24 hours ■ adults and children over 12 years: 2 softgels with water every 6 hours ■ children 4 to under 12 years: consult a doctor ■ children under 4 years: do not use.



VIVUNT™ 30 YEARS
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 8950 SW 74th Court, Suite 1901
 Miami, FL 33156-3178
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AXIV NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82706-016
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients	
Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	AXIV
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-016-01	3 in 1 CARTON	03/07/2024	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:82706-016-02	2 in 1 CARTON	03/07/2024	
2		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/07/2024	

Labeler - VIVUNT PHARMA LLC (045829437)