

**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 carton is open
- Tamper Evident: Do not use if carton or blister 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

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

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 Softgels** **Liquid-filled capsules



PACKAGE LABEL PRINCIPAL DISPLAY PANEL 100

Compare to VICKS® NyQuil®

Cold & Flu LiquiCaps®

active ingredients*

NDC 82706-016-03

AXIV NightTime Cold & Flu

Multi-Symptom Relief

Pain Reliever
 Fever Reducer
 Cough Suppressant
 Antihistamine

Nighttime Relief

Acetaminophen, Doxylamine Succinate, Dextromethorphan HBr

100 Softgels** **Liquid-filled capsules



Compare to Vicks[®] NyQuil[®] Cold & Flu LiquidCaps[®] active ingredients* NDC 62705-016-03

axiv

NightTime
 COLD & FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

NIGHTTIME RELIEF
 Acetaminophen
 Dextromethorphan HBr
 Doxylamine Succinate

100 SOFTGELS**
 **Liquid-filled capsules

axiv

NightTime
 COLD & FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
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axiv

NightTime
 COLD & FLU

Multi-Symptom Relief

- Pain Reliever
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Drug Facts

Active ingredients (in each softgel) Purpose
 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 upper throat and bronchial irritation
 • sore throat • headache • minor aches and pains
 • fever • cold, flu 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; • for more alcoholic drinks every day while using this product.
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin redness/• hives • rash. If a skin reaction occurs, stop use and seek medical help right away.
Severe drowsiness: If severe drowsiness or 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, 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) • 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

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are
 • taking the blood thinning drug warfarin
 • using medicine for malaria.

When using this product • do not use more than directed • drowsiness 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.
Accident 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. Check medication status in control for adults as well as for children even if you do not notice any signs or symptoms.

Directions
 • use only as directed (see overdose warning)
 • do not take more than 8 softgels in 24 hours

Other information
 • Store at 20°-25° (68°-77°F)
 • Tamper evident: Do not use if carton or pouch is open.

Inactive ingredients
 DSC: Yellow No. 10, FD&C Blue No. 1, Gelatin, Glycerin, Methylparaben, Polyethylene Glycol 400, Polydine K30, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Titanium Dioxide.

VIVUNT 30

Distributed by:
VIVUNT PHARMA LLC
 6950 SW 74th Court, Suite 1901
 Miami, FL 33156-3178
 Made in India.
www.vivunt.live

axiv

NightTime
 COLD & FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

50 Pouches of 2 softgels each





Principal display panel 50 softgels

Compare to VICKS® NyQuil®

Cold & Flu LiquiCaps®

active ingredients*

NDC 82706-016-04

AXIV NightTime Cold & Flu

Multi-Symptom Relief

Pain Reliever

Fever Reducer

Cough Suppressant

Antihistamine

Nighttime Relief

Acetaminophen, Doxylamine Succinate , Dextromethorphan HBr
 50 Softgels** **Liquid-filled capsules



Compare to Vicks[®] NyQuil[®] Cold & Flu LiquiCaps[®] active ingredients* NDC 82706-016-04

axiv

NightTime
COLD & FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

NIGHTTIME RELIEF
 Acetaminophen
 Dextromethorphan HBr
 Doxylamine Succinate

50 SOFTGELS**
 **Liquid-filled capsules

Compare to Vicks[®] NyQuil[®] Cold & Flu LiquiCaps[®] active ingredients* NDC 82706-016-04

axiv

NightTime
COLD & FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

Drug Facts

Active Ingredients (in each softgel)	Purpose
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, sinus and nasal pain, fever, runny nose and sneezing.

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you: **use more than 3 softgels in 24 hours**, which is the maximum daily amount for this product; **use other drugs containing acetaminophen**; or **use more alcohol**, extra every day while using this product.
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin rash, hives, blisters, itching, or severe reactions, stop use and seek medical help right away.
See throat warning: If sore throat is severe, lasts for more than 2 days, is accompanied or followed by fever, headache, rash, hoarseness, or swelling, 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, do not use this product. If you have ever had an allergic reaction to the product or any of its ingredients, do not use it again.

Ask a doctor before use if you have:
 liver disease; phenothiazines (drugs that cause drowsiness); a breathing condition or cough that does not go away with smoking, asthma, chronic bronchitis, or emphysema; or if you are taking any other prescription drug.

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; drowsiness may occur, especially in children; avoid alcohol; avoid driving a motor vehicle or operating machinery; avoid, bananas, and bismolans may increase drowsiness.

Stop use and ask a doctor if:
 you are coughing, sore or hoarse more than 7 days; fever gets worse or lasts more than 3 days; you experience or develop a rash; you experience sinus, 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.
 Observe warnings. In case of overdose, get medical help or contact a Poison Control Center right away. Cause: 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 3 softgels in 24 hours.
 Adults and children 12 years and over: 2 softgels with water every 6 hours.
 Children 6 to under 12 years: consult a doctor.
 Children under 6 years: do not use.

Other information
 Store at 20°-25°C (68°-77°F); excursions permitted: Do not use if carton is open.

Inactive ingredients
 Citric Acid, Croscarmellose, Docusone, Hydroxypropyl Cellulose, Hydroxypropyl Methylcellulose, Polyethylene Glycol 300, Polyethylene Glycol 400, Polyethylene Glycol 600, Polyethylene Glycol 800, Polyethylene Glycol 1000, Polyethylene Glycol 1500, Polyethylene Glycol 2000, Polyethylene Glycol 3000, Polyethylene Glycol 4000, Polyethylene Glycol 6000, Polyethylene Glycol 8000, Polyethylene Glycol 10000, Polyethylene Glycol 15000, Polyethylene Glycol 20000, Polyethylene Glycol 30000, Polyethylene Glycol 40000, Polyethylene Glycol 60000, Polyethylene Glycol 80000, Polyethylene Glycol 100000, Polyethylene Glycol 150000, Polyethylene Glycol 200000, Polyethylene Glycol 300000, Polyethylene Glycol 400000, Polyethylene Glycol 600000, Polyethylene Glycol 800000, Polyethylene Glycol 1000000.

Compare to Vicks[®] NyQuil[®] Cold & Flu LiquiCaps[®] active ingredients* NDC 82706-016-04

axiv

NightTime
COLD & FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

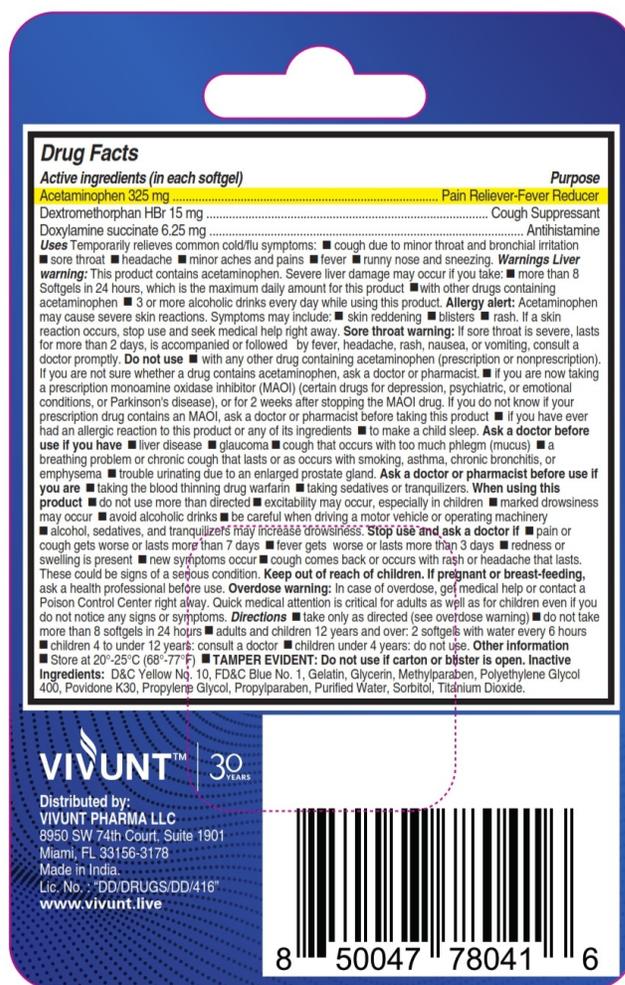


25 blisters of 2 softgels each

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VIVUNT 30

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 8950 SW 74th Court, Suite 1901
 Miami, FL 33156-3179
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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	03/07/2024
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:82706-016-03	50 in 1 CARTON	07/05/2024	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:82706-016-04	25 in 1 CARTON	02/12/2025	
4		25 in 1 BLISTER PACK; 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)