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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Axim Night Time Cold & Flu

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 & 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 4 doses 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.

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 & children 12 yrs & over	2 Softgela with water every 6 hrs
children 4 to under 12 yrs	consult a doctor
children under 4 yrs	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.

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

Product of India

Distributed by:

VIVUNT PHARMA LLC
8950 SW 74th. Court. Suite 1901

Miami, Florida. Z,C. 33156-3178

PRINCIPAL DISPLAY PANEL 24

Compare to VICKS ® NyQuil ®

Cold & Flu LiquiCaps®

active ingredients*

NDC 82706-002-01

- Pain Reliever
- Fever Reducer
- Cough Suppresant
- Antihistamine

Nighttime Relief

Acetaminophen, Doxylamine Succinate , Dextromethorphan HBr

24 LiquiCaps** **Liquid-filled capsules

PRINCIPAL DISPLAY PANEL

Compare to VICKS ® NyQuil ®

Cold & Flu LiquiCaps®

active ingredients*

NDC 82706-002-02

Pain Reliever
Fever Reducer
Cough Suppresant
Antihistamine

Nighttime Relief

Acetaminophen, Doxylamine Succinate , Dextromethorphan HBr

6 LiquiCaps** **Liquid-filled capsules

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

3 PORTABLE POUCHES
(2 Softgels per pouch)

axim

NightTime

COLD & FLU

Compare to Vicks® NyQuil® Cold & Flu LiquiCaps®
active ingredients*
NDC 82706-002-02

axim

NightTime

COLD & FLU

Multi-Symptom Relief

NIGHTTIME RELIEF

Acetaminophen
Dextromethorphan HBr
Doxylamine Succinate

6 SOFTGELS**
**Liquid-filled capsules

Drug Facts (continued)

Other information

■Store at 20°- 25°C (68- 77°F) ■Read all product information before using ■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.

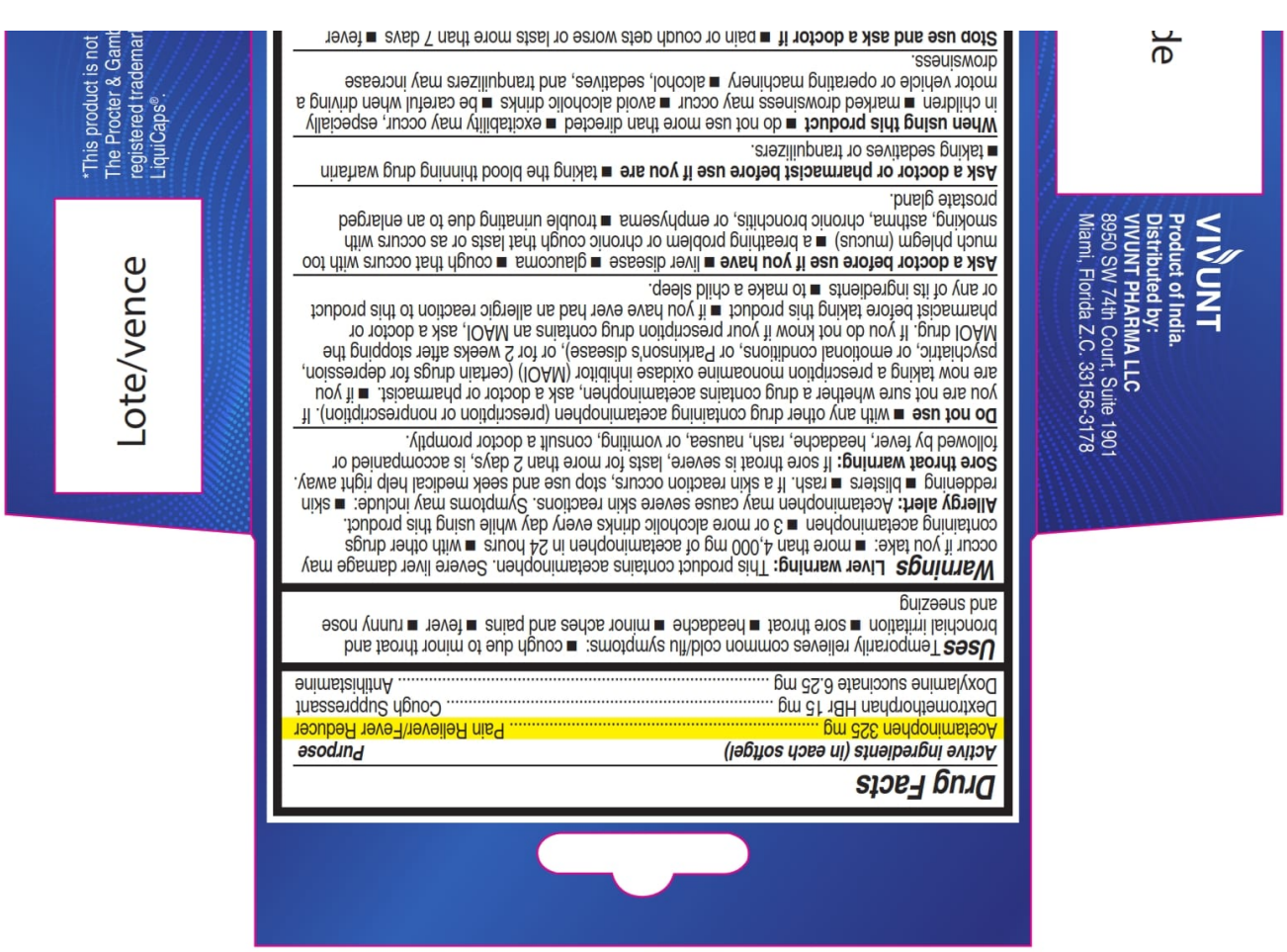
Directions ■take only as directed (see overdose warning) ■do not take more than 8 softgels in 24 hours ■adults and children over 12 years: 2 softgels with water every 6 hours ■children 4 to under 12 years: consult a doctor ■children under 4 years: do not use ▲

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.

cough gets worse or lasts more than 3 days ■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.

Barcode

Manufactured or distributed by
Procter & Gamble Company, owner of the
trademarks Vicks® NyQuil® Cold & Flu



AXIM NIGHT TIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82706-002
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: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (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**	axim
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-002-01	24 in 1 CARTON	05/09/2022	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:82706-002-02	3 in 1 CARTON	09/20/2023	
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 final	part341	05/09/2022	

Labeler - VIVUNT PHARMA LLC (045829437)

Revised: 9/2023 VIVUNT PHARMA LLC