

**AXIM SINUS SEVERE MUCUS- acetaminophen, guaifenesin, phenylephrine
hcl 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 - Sinus Severe + Mucus

Drug Facts

Active Ingredients (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever-Fever reducer
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

Temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:

- sinus congestion and pressure
- headache
- nasal congestion
- minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

Warnings

Liver warning

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy Alert:

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.

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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not exceed recommended dose

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion 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 accidental overdose, seek professional assistance or contact a poison control center immediately.

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 4 hours
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 or blister unit is broken.

Inactive ingredients

D&C Red No. 33, FD&C Red No. 40, 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 - AXIM Sinux Severe + Mucus 24

Compare Vicks[®] Sinex[™]

Severe All In One Sinus + Mucus[™] LiquiCaps[®]

active ingredients*

NDC 82706-006-01

AXIM Sinus Severe + Mucus

Cough & Congestion

- Pain Reliever
- Fever Reducer
- Expectorant
- Nasal Decongestant

NON-DROWSY

Acetaminophen, Guaifenesin, Phenylephrine HCl

24 SOFTGELS** **24 Liquid-filled Capsules

*This product is not manufactured or distributed by

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PRINCIPAL DISPLAY PANEL - AXIM Sinus Severe + Mucus 6

Compare Vicks® Sinex™

Severe All In One Sinus + Mucus™ LiquiCaps®

active ingredients*

NDC 82706-006-02

AXIM Sinus Severe + Mucus

Cough & Congestion

Pain Reliever

Fever Reducer

Expectorant

Nasal Decongestant

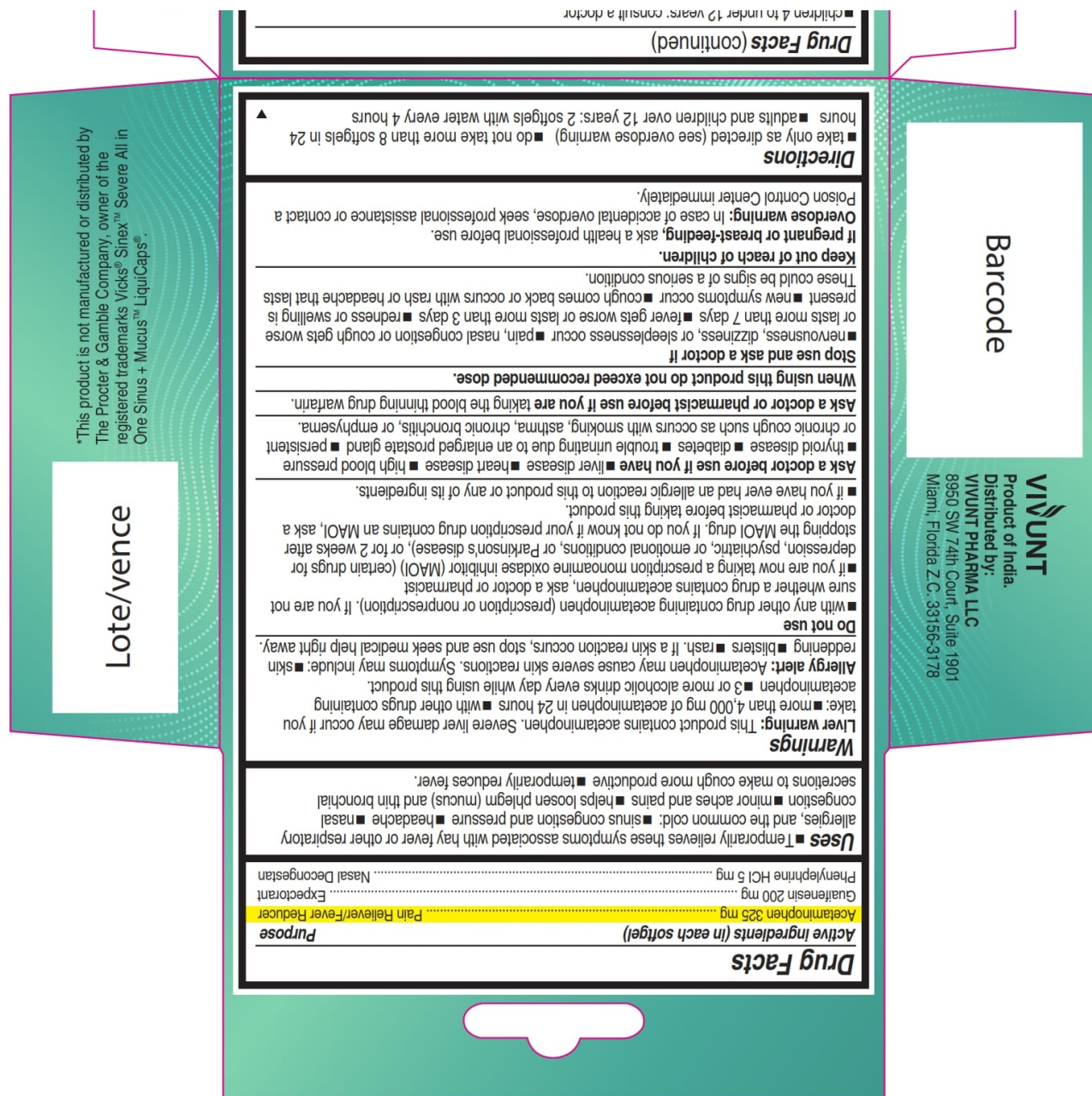
NON-DROWSY

Acetaminophen, Guaifenesin, Phenylephrine HCl

6 SOFTGELS** **24 Liquid-filled Capsules

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The Procter & Gamble Company, owner of the registered
trademarks Vicks® Sinex™ Severe All In One Sinus + Mucus™ LiquiCaps®





AXIM SINUS SEVERE MUCUS

acetaminophen, guaifenesin, phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82706-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	red	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:82706-006-01	2 in 1 CARTON	05/09/2022	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:82706-006-02	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)