

**AXIM SINUS SEVERE MUCUS- acetaminophen, guaifenesin, phenylephine
hcl capsule, liquid filled
VIVUNT PHARMA LLC**

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

The Procter &Gamble Company, owner of the registered

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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
METHYLPARABEN (UNII: A2I8C7HI9T)	
POVIDONE K30 (UNII: U725QWY32X)	
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	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 Drug	M012	05/09/2022	

Labeler - VIVUNT PHARMA LLC (045829437)

Revised: 6/2024

VIVUNT PHARMA LLC