

AXIV SINUS SEVERE MUCUS- acetaminophen, guaifenesin, phenylephrine hydrochloride capsule, liquid filled
VIVUNT PHARMA LLC

AXIV - 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 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:

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

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 12 years and over	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.
- Tamper Evident: Do not use if carton or pouch is open

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

Distributed by:

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

Miami, Florida, 33156-3178

Made in India

www.vivunt.live

PRINCIPAL DISPLAY PANEL - AXIM Sinux Severe + Mucus 24

Compare Vicks® Sinex™

Severe All In One Sinus + Mucus™ LiquiCaps®

active ingredients*

NDC 82706-020-01

AXIV Sinus Severe + Mucus

Cough & Congestion

Pain Reliever

Fever Reducer

Expectorant

Nassal Decongestant

NON-DROWSY

Acetaminophen, Guaifenesin, Phenylephrine HCl

24 SOFTGELS** **Liquid-filled Capsules

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 trademarks Vicks® Sinex™ Severe All In One Sinus + Mucus™ LiquiCaps®



PRINCIPAL DISPLAY PANEL - AXIV Sinus Severe + Mucus 4

Compare Vicks® Sinex™
 Severe All In One Sinus + Mucus™ LiquiCaps®
 active ingredients*

NDC 82706-020-02

AXIV Sinus Severe + Mucus

Cough & Congestion

Pain Reliever
 Fever Reducer
 Expectorant
 Nasal Decongestant

NON-DROWSY

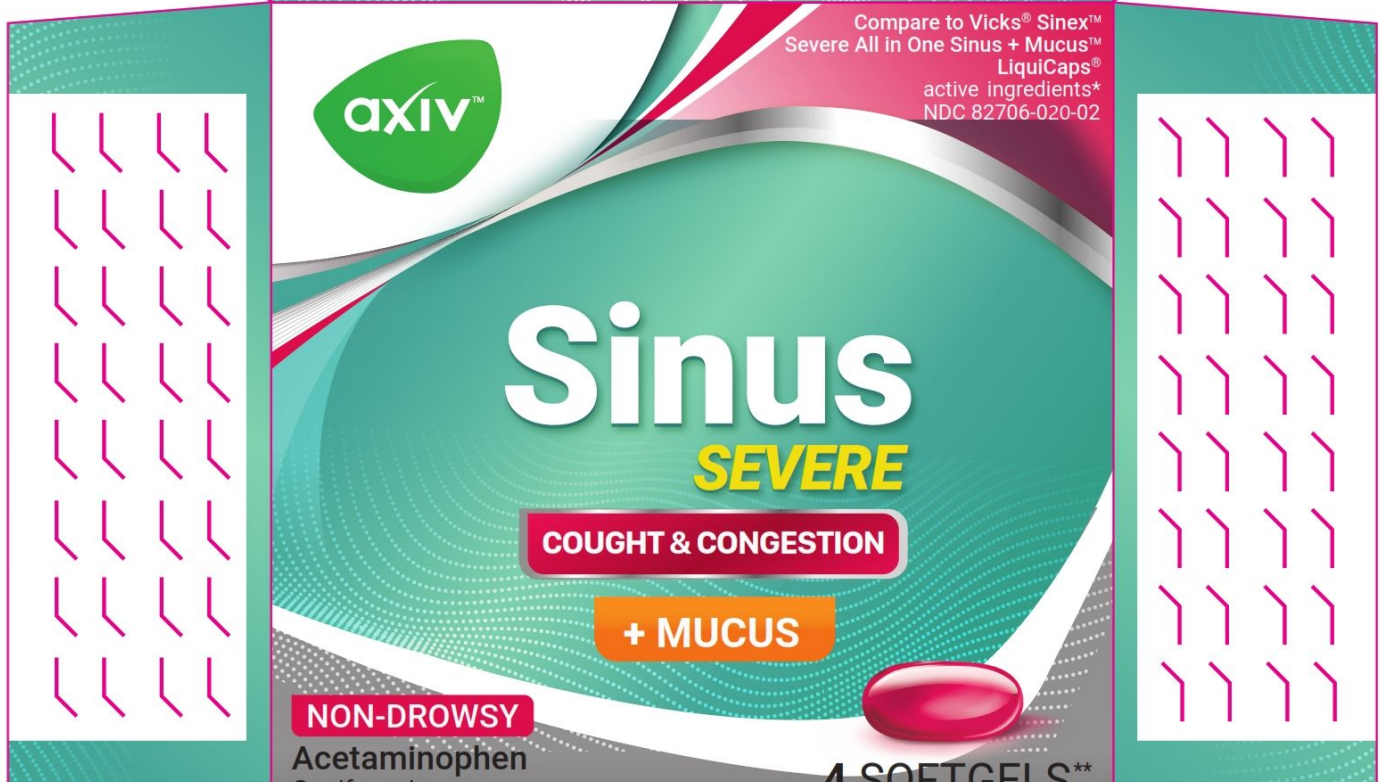
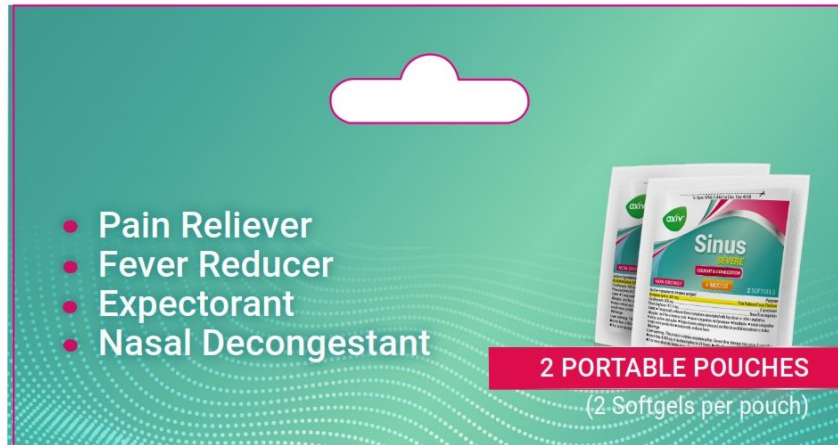
Acetaminophen, Guaifenesin, Phenylephrine HCl

4 SOFTGELS** **Liquid-filled Capsules

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trademarks Vicks® Sinex™ Severe All In One Sinus + Mucus™ LiquiCaps®



AXIV SINUS SEVERE MUCUS
 acetaminophen, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

Product Information

Guaifenesin
Phenylephrine HCl

***Liquid-filled capsules

Drug Facts (continued)

Drug Facts (continued)
 ■ 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 or pouch is open.
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.

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Guaifenesin 200 mgExpectorant
 Phenylephrine HCl 5 mgNasal Decongestant
 Acetaminophen 325 mgPain Reliever/Fever Reducer

Drug Facts
Active ingredients (in each softgel)
Purpose

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: 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.
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
Keep out of reach of children.
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 ▲

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 30 YEARS
VIVUNT™

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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 cough more productive ■ temporarily reduces fever.

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82706-020
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 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	AXIV
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-020-01	2 in 1 CARTON	03/08/2024	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:82706-020-02	2 in 1 CARTON	03/08/2024	
2		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M012	03/08/2024	

Labeler - VIVUNT PHARMA LLC (045829437)

Revised: 3/2024

VIVUNT PHARMA LLC