

**SINUS HEAD CONGESTION- acetaminophen, phenylephrine hydrochloride capsule, liquid filled**  
**VIVUNT PHARMA LLC**

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**AXIV Sinus Head Congestion**

***Active ingredients***

**Purpose**

<b><i>Active ingredients (in each softgel)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain Reliever-Fever reducer
Phenylephrine HCl 5 mg	Nasal Descongestant

***Uses***

- Temporarily relieves symptoms due to the common cold (or a cold)
- minor aches and pains
- headache
- fever
- nasal congestion
- sinus congestion & pressure
- temporarily relieves symptoms due to hay fever or other respiratory allergies

**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 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.

**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.

**Ask a doctor or pharmacist before use if you are**

Taking the blood thinning drug warfarin.

**Ask a doctor before use if you have**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland

**When using this product**

do not use more than directed

**Stop use and ask a doctor if**

- 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
- you get nervous, dizzy or sleepless

**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 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 exceed 8 softgels per 24 hrs

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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

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**Other information**

Do not exceed 25°C

**TAMPER EVIDENT: This package is safety sealed & child resistant. Use only if blisters are intact. If difficult to open, use scissors.**

***Inactive ingredients***

FD&C yellow no.6, Gelatin, Glycerin, Methylparaben, Polyethylene glycol 400, Povidone K 30, Propylene glycol, Propylparaben, Purified water, Sorbitol, Titanium Dioxide.

Compare to Vicks® Sinex TM

Severe All in One Sinus TM

Liquicaps®

active ingredients\*

NDC 82706-025-01

Sinus

HEAD CONGESTION

PRESSURE & PAIN

-Sinus Pressure

-Sinus Headache & Pain

-Sinus Congestion

-Stuffy Nose

NON-DROWSY

Acetaminophen

Phenylephrine HCl

24 SOFTGELS\*\*

\*\*Liquid-filled capsules

\*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademarks Vicks® Sinex TM All in One Sinus TM LiquiCaps®.

Lic. No. : "DD/DRUGS/DD/416"

VIVUNT TM

Distributed by: VIVUNT PHARMA LLC

8950 SW 74th Court, Suite 1901

Miami, FL 33156-3178. Made in India.

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## SINUS HEAD CONGESTION

acetaminophen, phenylephrine hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82706-025
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>METHYLPARABEN</b> (UNII: A2I8C7H9T)	

<b>POVIDONE K30</b> (UNII: U725QWY32X)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>SORBITOL</b> (UNII: 506T60A25R)
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)
<b>GELATIN</b> (UNII: 2G86QN327L)
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	AXIV
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-025-01	3 in 1 CARTON	03/18/2025	
1		8 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	03/18/2025	

**Labeler** - VIVUNT PHARMA LLC (045829437)

### Establishment

Name	Address	ID/FEI	Business Operations
SOFTECH PHARMA PRIVATE LIMITED		677111277	manufacture(82706-025)

Revised: 3/2025

VIVUNT PHARMA LLC