

SINUS PRESSURE AND PAIN- acetaminophen and phenylephrine hydrochloride tablet, coated

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e0ef968-dff3-4446-8412-8085677332f0>

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.

1120B-PRV-2020-0903

Drug Facts

| Active ingredients (in each caplet) | Purpose |
|--|-----------------------------|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Phenylephrine HCl 5 mg | Nasal decongestant |

Uses

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
 - sinus congestion and pressure
 - headache
 - minor aches and pains
 - nasal congestion
- promotes sinus drainage
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not exceed recommended dosage**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion 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

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see overdose warning)**

| | |
|--|---|
| adults and children 12 years and over | <ul style="list-style-type: none">▪ take 2 caplets every 4 hours▪ do not take more than 10 caplets in 24 hours |
|--|---|

children
under 12
years

- ask a doctor

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

Premier Value®

COMPARE TO THE ACTIVE INGREDIENTS IN SUDAFED PE® SINUS PRESSURE + PAIN†
NON-DROWSY

MAXIMUM STRENGTH

Sinus Pressure + Pain

Acetaminophen, Phenylephrine HCl

Pain Reliever/Fever Reducer, Nasal Decongestant

Relieves:

- Sinus Pressure & Congestion
- Sinus Headache

ACTUAL SIZE

24 CAPLETS

ON

ONZ

SINUS PRESSURE AND PAIN

acetaminophen and phenylephrine hydrochloride tablet, coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68016-173 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|--------|--------------|----------|
| Color | orange | Score | no score |
| Shape | OVAL | Size | 17mm |
| Flavor | | Imprint Code | AAA;1120 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68016-173-24 | 2 in 1 CARTON | 09/01/2020 | |
| 1 | | 12 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 final | part341 | 09/01/2020 | |

Labeler - <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e0ef968-dff3-4446-8412-8085677332f0> (101668460)

Revised: 12/2022

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