

SINUS RELIEF NON DROWSY- acetaminophen, phenylephrine hcl tablet, film coated
Publix Super Markets Inc

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.

Publix Super Markets, Inc. Sinus Relief Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
- headache
- sinus congestion and pressure
- nasal congestion
- minor aches and pains
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- 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: 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 • swallow whole – do not crush, chew or dissolve • do not take more than 10 caplets in 24 hours
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children under 12 years	ask a doctor
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Inactive ingredients

acesulfame potassium, carnauba wax, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Principal Display Panel

NON-DROWSY

sinus relief

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER

PHENYLEPHRINE HCl – NASAL DECONGESTANT

Relieves:

Sinus headache

Nasal congestion

Sinus pressure

FOR ADULTS

ACTUAL SIZE

Compare to the active ingredients in Tylenol® Sinus + Headache

24 CAPLETS

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NDC 56062-272-62

NON-DROWSY sinusrelief

**ACETAMINOPHEN - PAIN RELIEVER/FEVER REDUCER
PHENYLEPHRINE HCl - NASAL DECONGESTANT**

Relieves:

- Sinus headache
- Nasal congestion
- Sinus pressure

FOR ADULTS

24 CAPLETS



ACTUAL SIZE

*Compare to the active ingredients in Tylenol® Sinus + Headache

Important: Read all product information before using. Keep this box for important information.

27262 63 C9

<p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Active ingredients (in each caplet)</th> <th style="text-align: left;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Acetaminophen 325 mg.....</td> <td>Pain reliever/fever reducer</td> </tr> <tr> <td>Phenylephrine HCl 5 mg.....</td> <td>Nasal decongestant</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: <ul style="list-style-type: none"> ■ headache ■ sinus congestion and pressure ■ nasal congestion ■ minor aches and pains ■ helps decongest sinus openings and passages ■ promotes sinus drainage ■ helps clear nasal passages ■ temporarily reduces fever <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> ■ 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 <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. 	Active ingredients (in each caplet)	Purpose	Acetaminophen 325 mg.....	Pain reliever/fever reducer	Phenylephrine HCl 5 mg.....	Nasal decongestant	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ 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 <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</p> <p>When using this product do not exceed recommended dosage</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ nervousness, dizziness, or sleepiness 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 <p>These could be signs of a serious condition.</p> <p>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.</p>
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Phenylephrine HCl 5 mg.....	Nasal decongestant						

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN
 *This product is not manufactured or distributed by the owner of the registered trademark Tylenol®.
 Store at 20°-25°C (68°-77°F).

<p>Drug Facts (continued)</p> <p>Directions ■ do not take more than directed (see overdose warning)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 12 years and over</td> <td style="width: 50%;"> <ul style="list-style-type: none"> ■ take 2 caplets every 4 hours ■ swallow whole - do not crush, chew or dissolve ■ do not take more than 10 caplets in 24 hours </td> </tr> <tr> <td>children under 12 years</td> <td>ask a doctor</td> </tr> </table>	adults and children 12 years and over	<ul style="list-style-type: none"> ■ take 2 caplets every 4 hours ■ swallow whole - do not crush, chew or dissolve ■ do not take more than 10 caplets in 24 hours 	children under 12 years	ask a doctor	<p>Drug Facts (continued)</p> <p>Inactive ingredients acesulfame potassium, carnauba wax, croscollon, D&C yellow #1, aluminum lake, FD&C blue #1, aluminum lake, FD&C red #40, aluminum lake, flavor, lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide</p>
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SINUS RELIEF NON DROWSY

acetaminophen, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-272
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	16mm
Flavor	VANILLA (menthol)	Imprint Code	L272
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-272-62	12 in 1 CARTON	11/26/2007	
1		2 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
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OTC monograph final

part341

11/26/2007

Labeler - Publix Super Markets Inc (006922009)

Revised: 11/2020

Publix Super Markets Inc