

SINUS SEVERE- acetaminophen, guaifenesin, phenylephrine hcl tablet, 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 Severe Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Expectorant

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
- 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: 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 dosage

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.

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
children under 12 years	ask a doctor

Other information

- **each caplet contains:** sodium 4 mg
- store at 20-25°C (68-77°F)
- **do not use if blister unit is broken or torn**

Inactive ingredients

croscarmellose sodium, crospovidone, flavor, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, silicon dioxide, stearic acid, sucralose, titanium dioxide

Package/Label Principal Display Panel

NON-DROWSY

sinus severe

ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER

GUAIFENESIN – EXPECTORANT

PHENYLEPHRINE HCl – NASAL DECONGESTANT

Relieves:

Sinus headache

Nasal congestion

Sinus pressure

Chest congestion

FOR ADULTS

24 CAPLETS

ACTUAL SIZE

Compare to the active ingredients in Tylenol® Sinus Severe



NDC 56062-460-62

NON-DROWSY

sinussevere

**ACETAMINOPHEN – PAIN RELIEVER/FEVER REDUCER
GUAIFENESIN – EXPECTORANT
PHENYLEPHRINE HCl – NASAL DECONGESTANT**

Relieves:

- Sinus headache
- Nasal congestion
- Sinus pressure
- Chest congestion

FOR ADULTS

24 CAPLETS



ACTUAL SIZE

*Compare to the active ingredients in Tylenol® Sinus Severe

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

Drug Facts		Drug Facts (continued)	
Active ingredients (in each caplet)	Purpose	Uses	
Acetaminophen 325 mg.....	Pain reliever/fever reducer	■ temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:	
Guaifenesin 200 mg.....	Expectorant	■ sinus congestion and pressure	■ headache
Phenylephrine HCl 5 mg.....	Nasal decongestant	■ nasal congestion	■ minor aches and pains

Drug Facts (continued)	Drug Facts (continued)				
<ul style="list-style-type: none"> ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive ■ temporarily reduces fever 	<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 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 <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>				
<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. ■ 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 ■ trouble urinating due to an enlarged prostate gland ■ diabetes ■ persistent or chronic coughs such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough that occurs with too much phlegm (mucus) 	<p>Directions</p> <p>do not take more than directed (see overdose warning)</p> <table border="1"> <tr> <td>adults and children 12 years and over</td> <td> <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> <p>Other information</p> <ul style="list-style-type: none"> ■ each caplet contains: sodium 4 mg ■ store at 20-25° C (68-77° F) ■ do not use if blister unit is broken or torn 	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
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Drug Facts (continued)
Inactive ingredients croscarmellose sodium, oros povidone, flavor, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyorbate 80, povidone, pregelatinized starch, silicon dioxide, sodium benzoate, sucralose, titanium dioxide

*This product is not manufactured or distributed by the owner of the registered trademark Tylenol®.



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SINUS SEVERE

acetaminophen, guaifenesin, phenylephrine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-460
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-460-62	12 in 1 CARTON	01/05/2018	
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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Labeler - Publix Super Markets Inc (006922009)

Revised: 11/2020

Publix Super Markets Inc