

## **SINUS CONGESTION AND PAIN DAYTIME, NON-DROWSY- acetaminophen and phenylephrine hcl tablet**

**Walgreen Company**

*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.*

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**Walgreens 44-558**

### ***Active ingredients (in each gelcap)***

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 respiratory allergies, and the common cold:
  - headache
  - minor aches and pains
  - nasal congestion
  - sinus congestion and pressure
- 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 in 24 hours, which is the maximum daily amount
- 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
- thyroid disease
- heart disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- high blood pressure

**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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present

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.**

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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**
- adults and children 12 years and over
  - take 2 gelcaps every 4 hours
  - do not take more than 10 gelcaps in 24 hours
- children under 12 years: ask a doctor

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- avoid high humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

croscarmellose sodium, crospovidone, D&C yellow #10, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, silica gel, stearic acid, titanium dioxide

**Questions or comments?**

**1-800-426-9391**

**Principal Display Panel**

**Well at**

**Walgreens**

WALGREENS PHARMACIST RECOMMENDED<sup>□</sup>

NDC 0363-0558-08

**DAYTIME**

**NON-DROWSY**

**Sinus**

**Congestion & Pain**

**Acetaminophen** / Pain Reliever / Fever Reducer

Phenylephrine HCl / Nasal Decongestant

- Relieves headache, nasal congestion & sinus pressure

DAYTIME

**24**

**GELCAPS**

Actual Size

Compare to Tylenol® SINUS + HEADACHE Day active ingredients <sup>□□</sup>

**PSEUDOEPHEDRINE FREE**

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

<sup>□</sup>Walgreens Pharmacist Survey Study, November 2014.

<sup>□□</sup>This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® SINUS + HEADACHE Day.

50844 REV0216C55808

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

**Walgreens**

**100% SATISFACTION GUARANTEED**

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**DAYTIME  
NON-DROWSY**

# Sinus Congestion & Pain

**Acetaminophen / Pain Reliever / Fever Reducer  
Phenylephrine HCl / Nasal Decongestant**

• Relieves headache, nasal congestion & sinus pressure



WALGREENS PHARMACIST RECOMMENDED\*

NDC 0363-0588-08

B-2201-558-08-R  
REV0216C55808

**Drug Facts**

**Active ingredients (in each gelcap)**  
Acetaminophen 325 mg... Pain reliever/fever reducer  
Phenylephrine HCl 5 mg... Nasal decongestant

**Uses** ■ temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold: ■ headache ■ minor aches and pains ■ nasal congestion ■ sinus congestion and pressure

**Drug Facts (continued)**

**Warnings**  
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:  
■ more than 4,000 mg in 24 hours, which is the maximum daily amount  
■ 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 redness ■ blisters ■ rash  
If a skin reaction occurs, stop use and seek medical help right away.

**Drug Facts (continued)**

**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

**Drug Facts (continued)**

**Ask a doctor before use if you have** ■ liver disease ■ thyroid disease ■ heart disease ■ diabetes

**Drug Facts (continued)**

**Inactive ingredients** (continued)  
croscarmellose sodium, croscopolone, D&C yellow #10, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate.

**Drug Facts (continued)**

**Directions** ■ do not take more than directed adults and children 12 years and over  
■ take 2 gelcaps every 4 hours  
■ do not take more than 10 gelcaps in 24 hours  
■ children under 12 years: ask a doctor

**Other information**

■ **TAMPER EVIDENT: DO NOT USE IF OUTER OR PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN** ■ avoid high humidity  
■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)  
■ see end flap for expiration date and lot number

**Drug Facts (continued)**

**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 ■ new symptoms occur  
■ fever gets worse or lasts more than 3 days  
■ redness or swelling is present  
These could be signs of a serious condition. If pregnant or breast-feeding, ask a health professional before use.

**Drug Facts (continued)**

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

**Drug Facts (continued)**

**Other information**  
■ **TAMPER EVIDENT: DO NOT USE IF OUTER OR PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN** ■ avoid high humidity  
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TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

REV0913-RF\_R02

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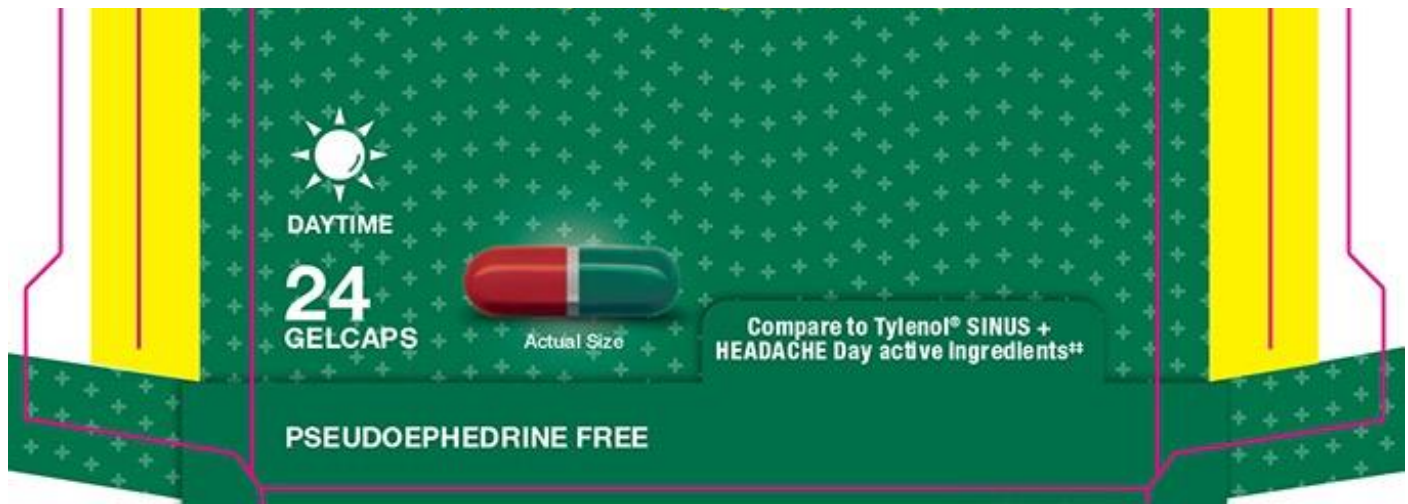
**Walgreens**

**100% SATISFACTION  
GUARANTEED**

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\* Walgreens Pharmacist Survey Study: November 2014.  
# This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® SINUS + HEADACHE Day.

50844 REV0216C55808



44-558

## SINUS CONGESTION AND PAIN DAYTIME, NON-DROWSY

acetaminophen and phenylephrine hcl tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0558
<b>Route of Administration</b>	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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	

### Product Characteristics

Color	RED, GREEN	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L;8
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0558-07	3 in 1 CARTON	03/17/2008	04/07/2023
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-0558-08	2 in 1 CARTON	03/17/2008	11/02/2019
2		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	03/17/2008	04/07/2023

**Labeler** - Walgreen Company (008965063)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0558)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0558)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0363-0558)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0363-0558)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0363-0558)

Revised: 5/2020

Walgreen Company