

## **SINUS CONGESTION AND PAIN DAYTIME- acetaminophen and phenylephrine hcl capsule NASH-FINCH 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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### **Our Family 44-558 Delisted**

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

Acetaminophen 325 mg  
Phenylephrine HCl 5 mg

#### **Purpose**

Pain reliever  
Nasal decongestant

#### **Uses**

- for the temporary relief of:
  - headache
  - sinus congestion and pressure
  - minor aches and pains
  - nasal congestion
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages

#### **Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 gelcaps 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

#### **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 before use if**

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

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

- 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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. 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**

- **do not take more than directed (see overdose warning)**
- adults and children 12 years and over
  - take 2 gelcaps every 4 hours
  - do not take more than 12 gelcaps in 24 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

**Other information**

- store at controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

**Inactive ingredients**

croscarmellose sodium, croscopovidone, 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

**Principal Display Panel**

Headache  
Sinus Pressure  
Nasal Congestion  
Non-Drowsy

Compare to the Active Ingredients in Tylenol® Sinus Congestion & Pain Daytime\*

**Our Family®**

Quality Care Since 1904

**DAY**

**Sinus**

**Congestion & Pain**

**Acetaminophen** - Pain Reliever

Phenylephrine HCl - Nasal Decongestant

QUICK RELEASE

24 GELCAPS

Does Not Contain Pseudoephedrine

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

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® Sinus Congestion & Pain Daytime.

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[www.ourfamilyfoods.com](http://www.ourfamilyfoods.com) NF18893

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**Drug Facts** (continued)

**Active Ingredients**  
 Acetaminophen 325 mg ..... Pain reliever  
 Phenylephrine HCl 5 mg ..... Nasal decongestant

**Purpose**  
 (in each gelcap)

**Drug Facts**  
 RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

**Uses** ■ for the temporary relief of: ■ headache  
 ■ sinus congestion and pressure  
 ■ minor aches and pains  
 ■ helps decongest sinus openings and passages  
 ■ promotes sinus drainage  
 ■ helps clear nasal passages

Headache  
 Sinus Pressure  
 Nasal Congestion  
 Non-Drowsy

**Our Family**<sup>®</sup>  
 Quality Care Since 1904

Compare to the Active  
 Ingredients in Tylenol<sup>®</sup>  
 Sinus Congestion  
 & Pain Daytime\*

# DAY Sinus Congestion & Pain

Acetaminophen - Pain Reliever  
 Phenylephrine HCl - Nasal Decongestant



24  
 GELCAPS

Does Not Contain  
 Pseudoephedrine



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

**Drug Facts** (continued)

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, polyethylene glycol, shellac, silica gel, stearic acid, titanium dioxide

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 & Pain Daytime.  
 registered trademark Tylenol<sup>®</sup> Sinus Congestion  
 by McNeil Consumer Healthcare, owner of the  
 \*This product is not manufactured or distributed

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 REV0712855808  
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■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

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

**Directions**  
 ■ do not take more than directed (see overdose warning)  
 ■ adults and children 12 years and over:  
 ■ take 2 gelcaps every 4 hours  
 ■ do not take more than 12 gelcaps in 24 hours  
 ■ children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

**Other information**  
 ■ 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, FD&C blue #1, FD&C croscardone, D&C yellow #10, FD&C blue #1, FD&C

damage, 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.



Our Family 44-558

## SINUS CONGESTION AND PAIN DAYTIME

acetaminophen and phenylephrine hcl capsule

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70253-558
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	RED	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	L;8

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70253-558-08	2 in 1 CARTON		
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 NOT FINAL	part343	03/17/2008	04/02/2018

**Labeler** - NASH-FINCH COMPANY (006962294)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(70253-558)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(70253-558)

Revised: 10/2015

NASH-FINCH COMPANY