

**SINUS AND HEADACHE- acetaminophen, phenylephrine hcl tablet, film coated**  
**Family Dollar Services Inc**

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**Family Wellness 44-466C**

***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 respiratory allergies, and the common cold:
  - headache
  - nasal congestion
  - minor aches and pains
  - 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:

- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash
- skin reddening

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**

- difficulty in urination due to enlargement of the prostate gland liver disease
- heart disease
- diabetes
- thyroid disease
- liver disease
- 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 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 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***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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***

corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

### ***Questions or comments?***

**1-800-426-9391**

### **Principal Display Panel**

FAMILY  
Wellness™

\*COMPARE TO THE  
ACTIVE INGREDIENTS  
IN TYLENOL® SINUS  
+ HEADACHE

DAYTIME  
**SINUS &  
HEADACHE**

**Acetaminophen**  
Phenylephrine HCl

Pain Reliever/Fever Reducer  
Nasal Decongestant

RELIEVES:  
• Sinus Headache  
• Sinus Pressure  
• Nasal Congestion

NON  
DROWSY

Pseudoephedrine free

**24** CAPLETS

ACTUAL SIZE

NDC 55319-496-08

**TAMPER EVIDENT: DO NOT**

**USE IF PACKAGE IS OPENED  
OR IF BLISTER UNIT IS  
TORN, BROKEN OR SHOWS  
ANY SIGNS OF TAMPERING**

\*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Tylenol® SINUS + HEADACHE. 50844 ORG072146608

**DISTRIBUTED BY: MIDWOOD BRANDS LLC,  
500 VOLVO PKWY, CHESAPEAKE, VA 23320 USA  
NOT 100% SATISFIED?**

Return within 30 days to the store of purchase for a refund (with receipt) or exchange.

**Lot no. & Exp. date**  
**No Print / No Varnish**

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNITS ARE BROKEN OR SHOW ANY SIGNS OF TAMPERING

B-0500-466C-08-N  
ORG072146608

**Drug Facts (continued)**

**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  
■ 3 or more alcoholic drinks every day while using this product  
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:  
■ hives ■ rash ■ skin redness  
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.  
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**Ask a doctor before use if you have**  
■ difficulty in urination due to enlargement of the prostate gland  
■ heart disease ■ diabetes ■ thyroid disease  
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**Drug Facts (continued)**

**Inactive ingredients** corn starch, croscopolone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, tlc, titanium dioxide

**Questions or comments?** 1-800-426-9391

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DAYTIME  
**SINUS & HEADACHE**

**Acetaminophen  
Phenylephrine HCl**

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Nasal Decongestant

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- Sinus Headache
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- Nasal Congestion

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NDC 55319-496-08

**Drug Facts (continued)**

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

**Drug Facts (continued)**

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

**Drug Facts (continued)**

**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 ■ redness or swelling is present  
■ fever gets worse or lasts more than 3 days  
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 right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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**Drug Facts (continued)**

**Warnings**  
■ helps decongest sinus openings and passages  
■ promotes sinus drainage ■ helps clear nasal passages  
■ temporarily reduces fever

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**Drug Facts (continued)**

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**Questions or comments?** 1-800-426-9391

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32251 92403 3

**Family Wellness 44-466C**

**SINUS AND HEADACHE**  
acetaminophen, phenylephrine hcl tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-496
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	44;466
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-496-08	2 in 1 CARTON	01/02/2024	
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 Drug	M012	01/02/2024	

**Labeler** - Family Dollar Services Inc (024472631)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(55319-496) , pack(55319-496)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(55319-496)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(55319-496)

Revised: 1/2024

Family Dollar Services Inc