# COLD AND HEAD CONGESTION RELIEF SEVERE- acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated WinCo Foods, LLC

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Winco 44-527C

#### Active ingredients (in each caplet)

Acetaminophen 325 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg

#### **Purpose**

Pain reliever/fever reducer Expectorant Nasal decongestant

#### Uses

- for the temporary relief of the following cold symptoms:
  - headache
  - nasal congestion
  - minor aches and pains
  - sore throat
  - sinus congestion and pressure
- 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:

- blisters
- rash
- skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is

accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### 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
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- heart disease
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- high blood pressure
- thyroid disease

#### 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

- redness or swelling is present
- 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
- 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.

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, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

#### Questions?

Call **1-800-824-1706** Monday – Friday 9am – 4pm MST

#### **Principal Display Panel**

#### **WinCo®**

**FOODS** 

\*Compare to the active ingredients in TYLENOL® Cold + Head Congestion Severe

#### **SEVERE**

#### Cold & Head Congestion Relief

Relieves: Headache, Fever, Stuffy Nose, Sinus Pressure, Chest Congestion, Mucus

#### ACETAMINOPHEN/

PAIN RELIEVER - FEVER REDUCER GUAIFENESIN / EXPECTORANT PHENYLEPHRINE HCI / NASAL DECONGESTANT

#### 24

Caplets

# 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 JOHNSON & JOHNSON CORPORATION, distributor of TYLENOL® Cold + Head Congestion Severe.

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**DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704** 

**100% SATISFACTION GUARANTEE** Comments & Questions? 800-824-1706

acid, sucralose, talc, titanium dioxide ■ see end flap for expiration date and lot number polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN Inactive ingredients corn starch, crospovidone, flavor, magnesium Other information - TAMPER EVIDENT: DO NOT USE IF OUTER (continued) size (continued) **Drug Facts** (continued) children under 12 years: ask a doctor ■ difficulty in urination due to enlargement of the prostate gland ■ do not take more than 10 caplets in 24 hours Ask a doctor before use if you have I liver disease diabetes ■ swallow whole - do not crush, chew, or dissolve ■ rake 2 caplets every 4 hours ■ adults and children 12 years and over ■ if you have ever had an allergic reaction to this product or any of its pharmacist before taking this product. ■ do not take more than directed do not know if your prescription drug contains an MAOI, ask a doctor or REV0820B527 Directions Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you (certain drugs for depression, psychiatric or emotional conditions, or adus ot symptoms. is critical for adults as well as for children even if you do not notice any ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) acetaminophen, ask a doctor or pharmacist. help or contact a Poison Control Center right away. Prompt medical attention ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains keep out of reach of children. In case of accidental overdose, get medical If pregnant or breast-feeding, ask a health professional before use. Do not use be signs of a serious condition. 0 DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704 cough comes back or occurs with rash or headache that lasts. These could consult a doctor promptly. is accompanied or followed by fever, headache, rash, nausea, or vomiting, 100% SATISFACTION GUARANTEE Comments & Questions? 800-824-1706 ■ fever gets worse or lasts more than 3 days ■ new symptoms occur Sore throat warning: If sore throat is severe, persists for more than 2 days, ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days If a skin reaction occurs, stop use and seek medical help right away. ■ nervousness, dizziness, or sleeplessness occur wsy include: ■ blisters ■ rash ■ skin reddening Stop use and ask a doctor if 

| Income Allergy alen: Acetaminophen may cause severe skin reactions. Symptoms When using this product do not exceed recommended dosage. 3 or more alcoholic drinks every day while using this product arug warrann. ■ with other drugs containing acetaminophen Ask a doctor or pharmacist before use if you are taking the blood thinning ■ more than 4,000 mg of acetaminophen in 24 hours may occur if you take bronchitis, or emphysema. I high blood pressure. I thyroid disease Liverwaming: This product contains acetaminophen. Severe liver damage persistent or chronic cough such as occurs with smoking, asthma, chronic Warnings cough that occurs with too much phiegm (mucus) **Drug Facts** (continued) **nund racts** (coununeg) сопдиг шоце ргодистие петрогату тедисея течет Vasal decongestant Рһепуерһіпе НСІ 5 тд ■ µelbs loosen phlegm (mucus) and thin pronchial secretions to make Expectorant Guaifenesin 200 mg ■ sore throat ■ sinus congestion and pressure ■ nasal congestion ■ minor aches and pains Purpose Active ingredients (in each caplet) USes In for the temporary relief of the following cold symptoms: Urug Facts МРЕЕТЕ РВОDUCT ІИГОВМАТІОИ **Drug Facts** (continued) KEEP OUTER PACKAGE FOR \*Compare to the active ingredients in TYLENOL® Cold + Head Congestion Severe WinCo Relieves: Headache, **SEVERE** Fever, Stuffy Nose, Sinus Pressure, Cold & Head Chest Congestion, Mucus **Congestion Relief** ACETAMINOPHEN/

PAIN RELIEVER - FEVER REDUCER
GUAIFENESIN/EXPECTORANT

PHENYLEPHRINE HCI/NASAL DECONGESTANT

Winco 44-527C

#### COLD AND HEAD CONGESTION RELIEF SEVERE

acetaminophen, quaifenesin, phenylephrine hcl tablet, film coated

Drug Facts

(continued)

**Questions?** Call **1-800-824-1706** Monday — Friday 9am — 4pm MST

YLENOL® Cold + Head Congestion Severe.

is not manufactured or distributed by JOHNSON

& JOHNSON CORPORATION, distributor of

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS

B-2150-527C-08-HC REV0820B52708

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-212	
Route of Administration	ORAL			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	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
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	19mm	
Flavor	MENTHOL	Imprint Code	44;527	
Contains				

I	Packaging					
4	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:67091- 212-24	2 in 1 CARTON	08/06/2005			
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	08/06/2005	

### Labeler - WinCo Foods, LLC (056098817)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(67091-212) , pack(67091-212)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(67091-212)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(67091-212)

Revised: 3/2024 WinCo Foods, LLC