

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

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 HCl / 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.

50844 REV0820B52708 WF2008

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

100% SATISFACTION GUARANTEE

Comments & Questions? 800-824-1706



SEVERE Cold & Head Congestion Relief

**ACETAMINOPHEN/
PAIN RELIEVER - FEVER REDUCER**

GUAIFENESIN/EXPECTORANT

PHENYLEPHRINE HCl/NASAL DECONGESTANT

24

Caplets

Winco 44-527C

Relieves: Headache,
Fever, Stuffy Nose,
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Compare to the active ingredients in
TYLENOL® Cold + Head Congestion Severe

Drug Facts (continued)

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active Ingredients (in each caplet)

Acetaminophen 325 mg Pain reliever/fever reducer

Guaifenesin 200 mg Expectorant

Phenylephrine HCl 5 mg Nasal decongestant

Purpose

■ 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

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■ 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 redness

■ 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.

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■ 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

Drug Facts (continued)

Directions

■ Do not take more than directed

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Drug Facts (continued)

Warnings

■ 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

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

■ 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.

Drug Facts (continued)

Other Information ■ TAMPER EVIDENT. DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

■ see end flap for expiration date and lot number

■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Drug Facts (continued)

Inactive Ingredients (continued)

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

Drug Facts (continued)

Questions? Call 1-800-924-1706

Monday - Friday 9am - 4pm MST

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

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704 50844 REV0820852708 WF2008

100% SATISFACTION GUARANTEE

Comments & Questions? 800-824-1706

No Print/No Varnish Lot & Expiry Area

0 70552 24129 9

* This product is not manufactured or distributed by JOHNSON & JOHNSON CORPORATION, distributor of TYLENOL® Cold + Head Congestion Severe.

B2150-527C-08-HC
REV0820852708

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: 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
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE, 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			

Packaging

#	Item 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)

Establishment

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

Establishment

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

Establishment

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

Revised: 3/2025

WinCo Foods, LLC