

COLD AND FLU RELIEF SEVERE- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
WinCo Foods, LLC

Winco 44-503A

Active ingredients (in each caplet)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - sore throat
 - cough
 - nasal congestion
 - headache
 - minor aches and pains
- 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:

- skin reddening
- blisters
- rash

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

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

- **each caplet contains:** sodium 3 mg
- **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, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions?

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

Principal Display Panel

WinCo[®]
FOODS

SEVERE
Cold & Flu
Relief

*Compare to the active ingredients
in **TYLENOL[®] Cold + Flu Severe**

Relieves: Headache, Fever,
Sore Throat, Nasal Congestion,
Cough, Mucus &
Chest Congestion

ACETAMINOPHEN/
PAIN RELIEVER - FEVER REDUCER
DEXTROMETHORPHAN HBr/
COUGH SUPPRESSANT
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**

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

* This product is not manufactured or distributed by KENVUE INC.,
distributor of TYLENOL® Cold + Flu Severe.

50844 REV0922C50308 WF1810

100% SATISFACTION GUARANTEE

Comments & Questions? 800-824-1706

0170552412812

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

No Print/ No Varnish Lot & Expiry Area

Drug Facts (continued)

Other information ■ each caplet contains: sodium 3 mg
 ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BUSTED 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

Drug Facts (continued)

Inactive ingredients com starch, croscollins, D&C yellow #10 aluminum lake, flavox, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, powder, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

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

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
 ■ 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 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
 ■ Ask a doctor or pharmacist if you are now taking a prescription non-narcotic (MAD) or (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAD drug. If you do not know if your prescription drug contains an MAD, 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 ■ heart disease ■ liver disease ■ diabetes ■ cough that occurs with too much phlegm (mucus)

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredients (in each caplet)
 Acetaminophen 325 mg ■ Pain reliever/fever reducer
 Dextromethorphan HBr 10 mg ■ Cough suppressant
 Guaifenesin 200 mg ■ Expectorant
 Phenylephrine HCl 5 mg ■ Nasal decongestant

Drug Facts (continued)

Uses ■ temporarily relieves these common cold and flu symptoms: ■ sore throat ■ cough ■ nasal congestion ■ headache
 ■ temporarily relieves these common cold and flu symptoms: ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive ■ temporarily reduces fever

*Compare to the active ingredients in **TYLENOL® Cold + Flu Severe**

Relieves: Headache, Fever, Sore Throat, Nasal Congestion, Cough, Mucus & Chest Congestion



24
Caplets

WinCo FOODS
SEVERE
Cold & Flu Relief

**ACETAMINOPHEN/
PAIN RELIEVER - FEVER REDUCER
DEXTROMETHORPHAN HBr/
COUGH SUPPRESSANT
GUAIFENESIN/EXPECTORANT
PHENYLEPHRINE HCl/NASAL DECONGESTANT**

Winco 44-503A

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

Keep out of reach of children. In case of 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.

If pregnant or breast-feeding, ask a health professional before use. Be signs of a serious condition.
 ■ fever gets worse or lasts more than 3 days
 ■ redness or swelling is present
 ■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

Stop use and ask a doctor if
 ■ new symptoms occur
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days
 ■ nervousness, dizziness, or sleeplessness occur

When using this product do not exceed recommended dosage.
 ■ Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.
 ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ thyroid disease ■ high blood pressure ■ difficulty in urination due to enlargement of the prostate gland

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704
 distributor of **TYLENOL® Cold + Flu Severe**,
 50844 REV0922C50308 WFL810
 100% SATISFACTION GUARANTEE
 Comments & Questions? 800-824-1706

PARENTS:
 Learn about teen medicine abuse
 www.Suppliermedicine.org

B-2150-503A-08-FLU
 REV0922C50308

COLD AND FLU RELIEF SEVERE
 acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-288
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 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)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
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	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor	MENTHOL	Imprint Code	44;503
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-288-24	2 in 1 CARTON	08/04/2005	
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	08/04/2005	

Labeler - WinCo Foods, LLC (056098817)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(67091-288) , pack(67091-288)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(67091-288)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(67091-288)

Revised: 8/2023

WinCo Foods, LLC