

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**

ACETAMINOPHEN/
PAIN RELIEVER - FEVER REDUCER

DEXTROMETHORPHAN HBr/
COUGH SUPPRESSANT
GUAIFENESIN/EXPECTORANT
PHENYLEPHRINE HCl/NASAL DECONGESTANT

24
Caplets

Relieves: Headache, Fever,

Comments & Questions? www.wincofoods.com



SEVERE
Cold & Flu Relief

ACETAMINOPHEN/
PAIN RELIEVER - FEVER REDUCER

DEXTROMETHORPHAN HBr/
COUGH SUPPRESSANT

GUAIFENESIN/EXPECTORANT

PHENYLEPHRINE HCl/NASAL DECONGESTANT

24
Caplets

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

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

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active Ingredients (in each caplet)

Acetaminophen 325 mg.....Pain reliever/fever reducer

Dextromethorphan HBr 10 mg.....Cough suppressant

Guafenesin 200 mg.....Expectorant

Phenylephrine HCl 3 mg.....Nasal decongestant

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- if you have ever had an allergic reaction to this product or any of its ingredients

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Drug Facts (continued)

Uses

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 - sore throat
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 - helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
 - temporarily reduces fever

Drug Facts (continued)

Warnings

- 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

- fever persists for more than 3 days
- 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.

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Drug Facts (continued)

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

Comments & Questions? www.wincofoods.com

100% SATISFACTION GUARANTEE

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

50844 REV09/22050308

owner of the registered trademark TYLENOL® Cold & Flu Severe.

This product is not manufactured or distributed by Kennebec Inc.

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

REV09/22050308

B-2150-5030A-08-48

WF2407

PARENTS: Learn about teen medicine abuse

www.StopMedicineAbuse.org

No Print/No Varnish Lot & EXP

0 70552 24128 2

WINCO 44-503A REV0922D

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 | | | | | | | | | | |
|---|---|----------------------|--------------------|--------------------|--|----------------------|--------------------|--------------------|------|------------|--|
| <div>Marketing Information</div> <table> <tr> <th>Marketing Category</th><th>Application Number or Monograph Citation</th><th>Marketing Start Date</th><th>Marketing End Date</th></tr> <tr> <td>OTC Monograph Drug</td><td>M012</td><td>08/04/2005</td><td></td></tr> </table> | | | | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | OTC Monograph Drug | M012 | 08/04/2005 | |
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| 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) |