

**COLD MULTI-SYMPTOM SEVERE- acetaminophen, dextromethorphan hbr, guaifenesin and phenylephrine hcl tablet, film coated
GREENBRIER INTERNATIONAL, INC.**

Assured 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
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- thyroid disease
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- 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, 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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°C-30°C (59°F-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 or comments?

1-800-426-9391

Principal Display Panel

ASSURED™

**DAYTIME
NON-DROWSY**

SEVERE

COLD

MULTI-SYMPTOM

- **Acetaminophen** - *Pain Reliever / Fever Reducer*
- Dextromethorphan HBr - *Cough Suppressant*
- Guaifenesin - *Expectorant*
- Phenylephrine HCl - *Nasal Decongestant*

*Fever, Headache, Sore Throat,
Coughing, Chest Congestion
& Nasal Congestion*

Actual Size

PSEUDOEPHEDRINE FREE

12 caplets
with Cool Blast flavor

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

50844 REV0718B50302

ITEM# 165711

Distributed by: **Greenbrier International, Inc.**
Chesapeake, VA 23320 USA

Drug Facts (continued)
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active Ingredients (in each caplet) Purpose
Acetaminophen 325 mg.....Pain reliever/fever reducer
Dextromethorphan Hbr 10 mg.....Cough suppressant
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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

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Drug Facts (continued)
Questions or comments? 1-800-426-9391

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SEVERE

COLD

MULTI-SYMPTOM

DAYTIME NON-DROWSY

- Acetaminophen - Pain Reliever / Fever Reducer
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Fever, Headache, Sore Throat, Coughing, Chest Congestion & Nasal Congestion



Actual Size
PSEUDOEPHEDRINE FREE

12 caplets
with Cool Blast flavor

8-0316-5034-02CMASR
REV0718B50302

Drug Facts (continued)

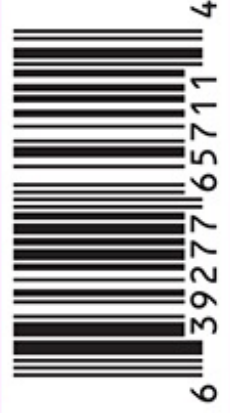
Other Information ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ see end flap for expiration date and lot number

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Drug Facts (continued)

■ 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

■ 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



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

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<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ thyroid disease ■ cough that occurs with too much phlegm (mucus) ■ difficulty in urination due to enlargement of the prostate gland ■ high blood pressure <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <p>When using this product do not exceed recommended dosage.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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. <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p>	<p>Directions ■ do not take more than directed</p>	<p>Warnings</p> <p>■ temporarily reduces fever</p> <p>Drug Facts (continued)</p> <p>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</p> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>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.</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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 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 the product
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44-503A

COLD MULTI-SYMPATOM SEVERE

acetaminophen, dextromethorphan hbr, guaifenesin and phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0503
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:33992-0503-2	1 in 1 CARTON	08/04/2005	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:33992-0503-8	2 in 1 CARTON	08/04/2005	
2		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 - GREENBRIER INTERNATIONAL, INC. (610322518)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(33992-0503) , pack(33992-0503)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(33992-0503)

Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		117025878	manufacture(33992-0503)
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Revised: 11/2023

GREENBRIER INTERNATIONAL, INC.