# COLD AND FLU SEVERE- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated Geiss, Destin & Dunn Inc.

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#### GoodSense 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 or comments?**

1-800-426-9391

#### Principal display panel

#### GOODSENSE®

#### NDC 50804-503-08

#### Cold + Flu Severe

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

Headache, Fever, Sore Throat, Cough, Nasal Congestion, Mucus, Chest Congestion

24 Caplets actual size

\*Compare to the active ingredients of Tylenol® COLD + FLU SEVERE

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® COLD + FLU SEVERE. 50844 REV0922C50308 Distributed by: Perrigo Direct, Inc., Peachtree City, GA 30269 www.PerrigoDirect.com (1-800-426-9391) GoodSense® is a registered trademark of L. Perrigo Company.

#### 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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Cyellow #10 licondocide, n diaxide		adaohe adaohe B-0550-5004-06V REV0922C50098	<b>24</b> Caplets		
GoodSense 44-503A					

## COLD AND FLU SEVERE

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

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-503	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 mg		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

mactive myreuents	Inactive	Ingredients
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Ingredient Name	Strength				
STARCH, CORN (UNII: 08232NY3SJ)					
CROSPOVIDONE, 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: FZ 989GH94E)					
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

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50804- 503-08	2 in 1 CARTON	06/09/2020	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
M	larketing	Information		

06/09/2020

# Labeler - Geiss, Destin & Dunn Inc. (076059836)

Establishment					
Name	Address	ID/FEI		Business Operations	
LNK International, Inc.		832867837	manufacture(	50804-503) , pack(50804-503)	
Establishment					
Name	Ad	dress	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		8	832867894	manufacture(50804-503)	
Establishment					
Name	Ad	dress	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		-	117025878	manufacture(50804-503)	

Revised: 1/2024

Geiss, Destin & Dunn Inc.