#### MAXIMUM STRENGTH COUGH AND CHEST CONGESTION AND NIGHTTIME SEVERE COLD AND FLU COMBO PACK- dextromethorphan hbr, guaifenesin, acetaminophen, doxylamine succinate Genexa Inc.

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Maximum Strength Cough and Chest Congestion and Nighttime Cold and Flu Severe Combo pack

#### Daytime Cough & Chest Congestion \*\*

#### Drug Facts

Active ingredients

#### (in each 20 mL)

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

#### Purposes

Cough suppressant

Expectorant

#### Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help you get to sleep

#### Warnings

**Do not use** 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.

# Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

#### When using this product do not use more than directed

**Stop use and ask a doctor if** cough lasts more than 7 days, comes back, or occurs with fever, 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 (1-800-222-1222).

#### • SHAKE WELL before each use

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

#### Other information

- store between 20-25°C (68-77°F)
- do not refrigerate

# Inactive ingredients

organic agave syrup, organic blueberry flavor, natural citrus extract, natural flavor, purified water

#### Questions? 1-855-436-3921

You may also report side effects to this phone number.

# Nighttime Cold & Flu\*

# **Drug Facts**

# Active ingredients (in each 20 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine Succinate 12.5 mg

# Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

#### Uses

- temporarily relieves these common cold and flu symptoms:
- cough due to minor throat and bronchial irritation
- minor aches and pains
- sore throat
- headache
- runny nose
- sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

# Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- 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 MAOI, ask a doctor or pharmacist before taking this product.

# Ask a doctor before use if you have

- liver disease
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- glaucoma
- trouble urinating due to enlarge prostate gland

# Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

# When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

# Stop use and ask a doctor if

• pain or cough gets worse or lasts more than 7 days

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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 overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

# Directions

- SHAKE WELL before each use
- only take as directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over children 4 to under 12 yrs children under 4 yrs 20 mL every 6 hours ask a doctor **do not use** 

#### Other information

- store between 20-25°C (68-77°F)
- do not refrigerate

# Inactive ingredients

organic agave syrup, organic blueberry flavor, organic chamomile extract, natural flavors, purified water

#### Questions? 1-855-436-3921

You may also report side effects to this phone number.

# DO NOT use if seal under the cap is disturbed or missing.

#### SHAKE WELL before each use.

\*U.S. Patent No. 11,617,795 | \*\*Patent Pending

Distributed by: Genexa Inc. Atlanta, GA 30324 | genexa.com

Made in the USA with globally sourced ingredients

NDC 69676-0079-3

# Day & Night Combo Pack

Genexa®

#### **MEDICINE MADE CLEAN**

Daytime

Maximum Strength **Cough & Chest Congestion Dextromethorphan HBr - Cough Suppressant Guaifenesin - Expectorant** Cough Mucus **Chest Congestion** Nighttime Severe • Maximum Strength Nighttime Cold & Flu Acetaminophen - Pain Reliever/Fever Reducer **Dextromethorphan HBr - Cough Suppressant Doxylamine Succinate - Antihistamine** Fever Headache Sore Throat **Body Aches & Pains** Cough Sneezing **Runny Nose** Medicine made clean Same effective active ingredients, but no artificial fillers. TWO - 6 fl oz (177 mL) bottles | TOTAL - 12 fl oz (355 mL)



# MAXIMUM STRENGTH COUGH AND CHEST CONGESTION AND NIGHTTIME SEVERE COLD AND FLU COMBO PACK

dextromethorphan hbr, guaifenesin, acetaminophen, doxylamine succinate kit

#### **Product Information**

 Product Type
 HUMAN OTC DRUG
 Item Code (Source)
 NDC:69676-0079

Packaging

	rackaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:69676- 0079-3	2 in 1 KIT	05/31/2024					
1		1 in 1 BOTTLE; Type 0: Not a Combination Product						

#### **Quantity of Parts**

	<b>(</b>				
Part # Package Quantity Total Product Quantity					
Part 1   1 BOTTLE, PLASTIC   177 mL					
Part 2         1 BOTTLE         177 mL					

# Part 1 of 2

# **COUGH AND CHEST CONGESTION MAXIMUM STRENGTH**

dextromethorphan hbr, guaifenesin suspension

Product Info	rmation					
ltem Code (Sou	urce)	NDC:69676-0077				
Route of Admir	nistration	ORAL				
Active Ingred	liont/Active	Mojety				
Active mgree		dient Name		Basis of Stre	nath	Strengt
	-				ingtin	400 mg
		)) (GUAIFENESIN - UNII:495W7451VC	2)	GUAIFENESIN		in 20 mL
<b>DEXTROMETHOR</b> (DEXTROMETHORP		ROMIDE (UNII: 9D2RTI9KYH) X3ROTS)		DEXTROMETHORPH HYDROBROMIDE	IAN	20 mg in 20 mL
Inactive Ingr	odionts					
mactive mgr	eulents	Ingredient Name			C+	rength
BLUEBERRY (UNII	· 253BUG1X1A)				51	engti
CITRUS FRUIT (U		2)				
<b>WATER</b> (UNII: 059						
AGAVE TEQUILAN	NA JUICE (UNII:	GVG8G0207O)				
Product Chai	racteristics					
Color	brow	n (Golden) Score				
Shape			Size			
Flavor BLUE		BERRY Imprint Code				
Contains						
Packaging						
	_	In	M	larketing Start	Mark	eting End
# Item Code	Р	ackage Description		Date		Date
1 NDC:69676- 0077-9	177 mL in 1 BC Combination Pr	OTTLE, PLASTIC; Type 0: Not a				
0077 5	combination m	oddet				
Marketing	Informat	tion				
Marketing Category		ition Number or Monograph Citation	Ma	arketing Start Date		eting End Date
OTC Monograph D	rug M013	citation	02/1	2/2024		Dutt
	lag lieis		02/1	2,2021		
Dart 2 of 2						
Part 2 of 2	-					
NIGHTTIM	E SEVERE	COLD AND FLU				
acetaminopher	n, dextrometh	orphan hydrobromide, doxyl	amine	succinate suspe	ension	

# **Product Information**

ltem	Code	(Source)
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NDC:69676-0094

Route of Administration

ORAL

<b>Active Ingredient/Acti</b>	ive Moiety				
Ing	gredient Name		<b>Basis of Stren</b>	gth	Strength
ACETAMINOPHEN (UNII: 3620	99ITL9D) (ACETAMINOPHEN - UNII:36209	OITL9D) AG	CETAMINOPHEN		650 mg in 20 mL
DEXTROMETHORPHAN HYDE (DEXTROMETHORPHAN - UNII:73	ROBROMIDE (UNII: 9D2RTI9KYH) 355X3ROTS)		EXTROMETHORPHAN YDROBROMIDE	N	30 mg in 20 mL
<b>DOXYLAMINE SUCCINATE</b> (U UNII:95QB77JKPL)	NII: V9BI9B5YI2) (DOXYLAMINE -	D	OXYLAMINE SUCCIN	IATE	12.5 mg in 20 mL
Inactive Ingredients	Ingredient Name			Str	ength
WATER (UNII: 059QF0KO0R)				50	ength
CHAMOMILE (UNII: FGL3685T2	2X)				
AGAVE TEQUILANA JUICE (UN	NII: GVG8G0207O)				
BLUEBERRY (UNII: 253RUG1X	1A)				
Product Characteristi	cs				
Color	brown (Light) Sc	ore			
Chana	<b>C</b> :				

Color	brown (Light)	Score	
Shape		Size	
Flavor	BLUEBERRY	Imprint Code	
Contains			

# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:69676- 0094-9	177 mL in 1 BOTTLE; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M013	05/31/2024			

Revised: 5/2024

Genexa Inc.