DAYTIME AND NIGHTTIME KIDS MULTI-SYMPTOM COLD AND FLU COMBO PACK- acetaminophen, dextromethorphan hbr, diphenhydramine hcl Genexa Inc.

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Daytime and Nighttime Kids' Multi-Symptom Cold & Flu Combo pack Kids' Nighttime Multi-Symptom Cold & Flu

**Drug Facts** 

Active ingredients

(in each 10 mL)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

## **Purposes**

Pain reliever/fever reducer

Antihistamine/Cough Suppressant

#### Uses

temporarily reduces fever and relieves these common cold/flu symptoms:

minor aches and pains

headache

cough due to minor throat and bronchial irritation

sore throat

runny nose

sneezing

controls the impulse to cough to help your child get to sleep

## Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**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.
- with any other product containing diphenhydramine, even one used on skin

#### Ask a doctor before use if the child has

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus).

## Ask a doctor or pharmacist before use if the child is

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

## When using this product

- do not use more than directed
- marked drowsiness may occur
- sedatives and tranquilizers may increase the drowsiness effect
- excitability may occur, especially in children

## Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

# Keep out of reach of children.

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical even if you do not notice any signs or symptoms.

#### **Directions**

- this product does not contain directions or complete warnings for adult
- do not give more than directed (see Overdose warning)
- SHAKE WELL before each use
- for accurate dosing, use measuring cup provided. Do not use with any other dosing device.
- children 6 to under 12 years of age: 10 mL in dosing cup provided every 4 hours while symptoms last, do not give more than 5 times in 24 hours
- children under 6 years of age: do not use unless directed by a doctor

#### Other information

store between 20-25°C (68-77°F)

#### Inactive ingredients

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

**Questions?** 1-855-436-3921

SHAKE WELL before each use.

Keep outer package for complete product information

Tamper evident: Do not use if perforated band around the bottle is disturbed or missing.

Kids' Multi-Symptom Cold & Flu - Daytime Relief

**Drug Facts** 

**Active ingredients** 

(in each 10 mL)

Acetaminophen 320 mg

Dextromethorphan HBr, USP 5 mg

## **Purposes**

Pain reliever/fever reducer

Cough Suppressant

#### Uses

- temporarily reduces fever and relieves these common cold/flu symptoms:
- minor aches & pains
- headache
- cough due to minor throat and bronchial irritation
- sore throat
- controls the impulse to cough to help your child get to sleep

# Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 2 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**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.
- in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

#### Ask a doctor before use if the child has

- liver disease
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus).

# Ask a doctor or pharmacist before use if the child is taking the blood thinning drug warfarin

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

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

# 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 even if you do not notice any signs or symptoms.

#### **Directions**

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see Overdose warning)
- SHAKE WELL before each use
- find right dose on chart below
- for accurate dosing, use measuring cup provided. Do not use with any other dosing device.
- give dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

children 6 to under 12 years	10 mL every 4 hours
children 4 to under 6 years	7.5 mL every 4 hours
children under 4 years	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

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

genexa.com | U.S. Patent No. 11,617,795

Made in the USA with globally sourced ingredients

NDC 69676-0092-3

**DAYTIME + NIGHTTIME VALUE PACK** 

**Genexa®** 

**MEDICINE MADE CLEAN** 

Ages 4+

Kids' Multi-Symptom Cold & Flu Daytime Relief

Acetaminophen - Pain Reliever/Fever Reducer

**Dextromethorphan HBr 5mg - Cough Suppressant** 

**Fever** 

Headache

**Body Aches & Pains** 

Sore Throat

Cough

Medicine made clean

Same effective active ingredients, but no artificial fillers.

Organic Blueberry Flavor

Ages 6+

Kids' Nighttime Multi-Symptom Cold & Flu

**Acetaminophen - Pain Reliever/Fever Reducer** 

Diphenhydramine HCI - Antihistamine/Cough Suppressant

**Fever** 

Sore Throat

**Body Pain** 

Cough

Runny Nose

Sneezing

Medicine made clean

Same effective active ingredients, but **no artificial fillers.** 

## **Organic Blueberry Flavor**

#### TWO - 4 FL OZ (118 mL) BOTTLES

**TOTAL - 8 FL OZ (236 mL)** 



# DAYTIME AND NIGHTTIME KIDS MULTI-SYMPTOM COLD AND FLU COMBO PACK

acetaminophen, dextromethorphan hbr, diphenhydramine hcl kit

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69676-0092

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69676- 0092-3	2 in 1 KIT	06/25/2024	
1		1 in 1 BOTTLE; Type 0: Not a Combination Product		

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity

Part 1	1 BOTTLE	118 mL
Part 2	1 BOTTLE	118 mL

# Part 1 of 2

# KIDS MULTI SYMPTOM COLD AND FLU

acetaminophen, dextromethorphan hbr suspension

## **Product Information**

Item Code (Source) NDC:69676-0096

**Route of Administration** ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 10 mL	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	320 mg in 10 mL	

Strength

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

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	<b>1</b> NDC:69676-0096-9	118 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		

# Part 2 of 2

# KIDS NIGHTTIME MULTI SYMPTOM COLD AND FLU

acetaminophen, diphenhydramine hcl suspension

#### **Product Information**

Item Code (Source) NDC:69676-0091

**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 in 10 mL	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 10 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BLUEBERRY (UNII: 253RUG1X1A)		
WATER (UNII: 059QF0KO0R)		
AGAVE TEQUILANA JUICE (UNII: GVG8G02070)		

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

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:69676- 0091-9	118 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	06/25/2024			

Labeler - Genexa Inc. (079751024)

Revised: 9/2024 Genexa Inc.