CORICIDIN HBP MAXIMUM STRENGTH COLD, COUGH AND FLUacetaminophen, dextromethorphan hydrobromide, doxylamine succinate Bayer HealthCare LLC.

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Coricidin HBP Maximum Strength Cold , Cough & Flu Day/Cold & Flu Night Bundle UIs 1615257/1614785

#### **Product Name**

Coricidin HBP Max Strength Cold, Cough, and Flu

Active ingredients (in each 30 mL)	Purposes
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan hydrobromide 20 mg	Cough suppressant

#### Uses

- temporarily relieves these symptoms due to a cold or flu:
  - minor aches and pains
  - headache
  - cough
  - sore throat
- 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 or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- hives
- facial swelling
- asthma (wheezing)
- shock

If a skin or general allergic 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
- in children under 12 years of age

## Ask a doctor before use if you have

- liver disease
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that is accompanied with excessive phlegm (mucus)
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

## 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. Quick 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 recommended dose
- adults and children 12 years and over: take 30 mL in the dosing cup provided every 4 hours. Do not exceed 150 mL (5 doses) in 24 hours or as directed by a doctor.
- children under 12 years of age: do not use

#### Other information

- each 30 mL contains: sodium 38 mg
- store between 20° to 25°C (68° to 77°F)

**Inactive ingredient**s anhydrous citric acid, FD&C blue #1, FD&C red # 40, flavor, glycerin, maltitol solution, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments? 1-800-317-2165 (Mon - Fri 9AM - 5PM EST)

## **Product Name**

Active ingredients (in each 30mL)	Purposes
Acetaminophen 650mg	Pain reliever/fever reducer
Dextromethorphan hydrobromide 20mg	Cough suppressant
Doxylamine succinate 12.5mg	Antihistamine

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains
- headache
- cough
- sore throat
- runny nose
- sneezing
- 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 or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- hives
- facial swelling
- asthma (wheezing)
- shock

If a skin or general allergic 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 to sedate children

#### 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
- in children under 12 years of age

## Ask a doctor befpre ise if you have

- liver disease
- glaucoma
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem sich as emphysema or chronic bronchitis
- cough that occurs with excessive phlegm (mucus)
- a sodium-restricted diet

## Ask a doctor or pharmacist before use if you are

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

## When using this product

- 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. Quick 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 recommended dose
- adults and children 12 years and over: take 30 mL in the dosing cup provided every 4 hours. Do not exceed 150 mL (5 doses) in 24 hours or as directed by a doctor.
- children under 12 years of age: do not use

#### Other information

- each 30 mL contains: sodium 38 mg
- store between  $20^{\circ}$  to  $25^{\circ}$ C ( $68^{\circ}$  to  $77^{\circ}$ F)

**Inactive ingredients** anhydrous sitric acid, FD&C blue #1, FD&C red#40, flavor, glycerin, maltitol solution, polyethylene glycol, propylene glycol, purified water, saccharin

# **Questions or comments? 1-800-317-2165** (Mon - Fri 9AM - 5PM EST)



# CORICIDIN HBP MAXIMUM STRENGTH COLD, COUGH AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11523-0124

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# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:11523- 0124-1	1 in 1 CARTON; Type 0: Not a Combination Product	05/12/2025	

### **Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	355 mL
Part 2	1 BOTTLE	355 mL

## Part 1 of 2

# **CORICIDIN HBP MAXIMUM STRENGTH NIGHTTIME COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product	Intorm	STION
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Item Code (Source) NDC:11523-0077

**Route of Administration** ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	

Inactive Ingredients	
Ingredient Name	Strength
MALTITOL (UNII: D65DG142WK)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:11523- 0077-1	355 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	M012	04/27/2022		

## Part 2 of 2

# CORICIDIN HBP MAXIMUM STRENGTH COLD, COUGH AND FLU

acetaminophen, dextromethorphan hydrobromide liquid

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Item Code (Source) NDC:11523-0093

**Route of Administration** ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	

Inactive Ingredients			
Ingredient Name	Strength		
MALTITOL (UNII: D65DG142WK)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
GLYCERIN (UNII: PDC6A3C0OX)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
WATER (UNII: 059QF0KO0R)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11523- 0093-1	355 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	M012	04/27/2022				

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

# Labeler - Bayer HealthCare LLC. (112117283)

Revised: 5/2025 Bayer HealthCare LLC.