CORICIDIN HBP MAXIMUM STRENGTH COLD AND FLU DAY AND NIGHTacetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate

**Bayer HealthCare LLC.** 

-----

Coricidin HBP Maximum Strength Cold & Flu Day & Night Liquigels UI 1614532 and UI 1614533

Coricidin HBP® Maximum Strength Cold & Flu Day Liquid Gels

**Drug Facts** 

#### **Active ingredients**

#### Active ingredients (in each capsule) Purposes

Acetaminophen 325 mg.......Pain reliever/fever reducer

Dextromethorphan hydrobromide 10 mg.....Cough suppressant

Guaifenesin 200 mg.....Expectorant

#### **Purpose**

#### Uses

#### Uses

- · temporarily relieves these symptoms due to a cold or flu:
- · minor aches and pains · headache · cough
- · sore throat
- · helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make cough more productive
- · temporarily reduces fever

#### Warnings

#### Warnings

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

- $\cdot$  more than 4,000 mg of acetaminophen in 24 hours
- $\cdot$  with other drugs containing acetaminophen
- $\cdot$  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

#### 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

#### Aska a doctor

## Ask a doctor before use if you have

- liver disease
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough with excessive phlegm (mucus)

## Ask a doctor or pharmacist

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

#### Stop use

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
- $\cdot$  cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

#### If pregnant or breast-feeding

**If pregnant or breast-feeding,** ask a health professional before use.

#### Keep out of reach of children

**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**

#### **Directions**

- · do not take more than the recommended dose
- $\cdot$  do not take the Day and Night products at the same time; wait 4 hours after taking the last Night dose before taking the Day product.
- · adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 6 capsules in 12 hours or as directed by a doctor.
- · children under 12 years of age: do not use

#### Other information

#### Other information

· store at 15°-25°C (59°-77°F)

## Inactive ingrediens

**Inactive ingredients** FD&C red No.40, gelatin, glycerin, iron oxide black, lecithin, medium-chain triglycerides, polyethylene glycol, potassium aluminum silicate, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

#### **Questions or comments?**

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

# Coricidin® HBP Maximum Strength Cold & Flu Night Liquid Gels Drug Facts

#### **Active ingredients**

#### Active ingredients (in each capsule)Purposes

Acetaminophen 325 mg......Pain reliever/fever reducer

Dextromethorphan hydrobromide 10 mg.....Cough suppressant

Doxylamine succinate 6.25 mg.....Antihistamine

#### Uses

#### Uses

- · 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

#### 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
- $\cdot$  with other drugs containing acetaminophen
- $\cdot$  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

#### 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 Ask a doctor before use if you have

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

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

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

## When using this product When using this product

- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

## Stop use and ask a doctor if

#### 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
- $\cdot$  cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition

#### If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

#### Keep out of reach of children

**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**

#### **Directions**

- · do not take more than the recommended dose
- · do not take the Day and Night products at the same time; wait 4 hours after taking the last Day dose before taking the Night product.
- · adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 4 capsules in 12 hours or as directed by a doctor.
- · children under 12 years of age: do not use

#### Other information

#### Other information

· store at 15°-25°C (59°-77°F)

#### **Questions or Comments**

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

Coricidin® HBP

COLD RELIEF FOR PEOPLE WITH HIGH BLOOD PRESSURE

#### **MAXIMUM STRENGTH**

#### **COLD & FLU DAY**

#### **GUAIFENESIN - Expectorant**

#### **DEXTROMETHORPHAN HBr - Cough Supressant**

#### ACETAMINOPHEN - Pain Reliever/Fever Reducer

#### Relieves

- Body Aches & Pains
- Headache
- Chest Congestant
- Cough
- Sore Throat
- Fever

### **†** Decongestant Free

16 LIQUID GELS

(Liquid Filled Capsules)

#### **COLD & FLU NIGHT**

**DOXYLAMINE SUCCINATE - Antihistamine** 

**DEXTROMETHORPHAN HBr - Cough Suppresant** 

ACETAMINOPHEN - Pain Reliever/Fever Reducer

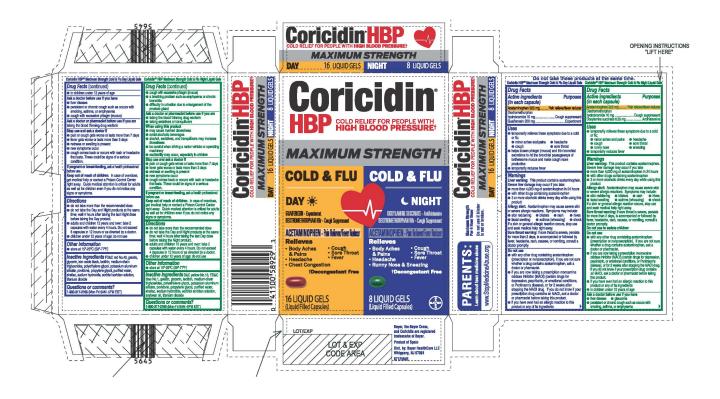
#### **RELIEVES**

- Body Aches & Pains
- Headache
- Runny Nose & Sneezing
- Cough
- Sore Throat
- Fever

#### **†** Decongestant Free

**8 LIQUID GELS** 

(Liquid Filled Capsules)



## CORICIDIN HBP MAXIMUM STRENGTH COLD AND FLU DAY AND NIGHT

acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11523-0026

## **Packaging**

#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523- 0026-1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/01/2020	

#### **Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	8
Part 2	2 BLISTER PACK	4

#### Part 1 of 2

#### CORICIDIN HBP MAXIMUM STRENGTH COLD AND FLU DAY

acetaminophen, dextromethorphan hydrobromide, guaifenesin capsule, liquid filled

#### **Product Information**

**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	10 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		

Inactive Ingredients				
Ingredient Name	Strength			
SHELLAC (UNII: 46N107B710)				
SORBITOL (UNII: 506T60A25R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
WATER (UNII: 059QF0KO0R)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
SORBITAN (UNII: 6092ICV9RU)				
IRON (UNII: E1UOL152H7)				
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)				
POVIDONE (UNII: FZ 989GH94E)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
GELATIN (UNII: 2G86QN327L)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
GLYCERIN (UNII: PDC6A3C0OX)				

Product Characteristics				
Color red Score no score				
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	CHBPD	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M012	07/01/2020			

#### Part 2 of 2

## CORICIDIN HBP MAXIMUM STRENGTH COLD AND FLU NIGHT

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

#### **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg			
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg			

Inactive Ingredients				
Ingredient Name	Strength			
POTASSIUM ALUMINUM DISILICATE (UNII: SRB14JRX6C)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
SHELLAC (UNII: 46N107B710)				
SORBITAN (UNII: 6092ICV9RU)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
POVIDONE (UNII: FZ 989GH94E)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
SORBITOL (UNII: 506T60A25R)				
SOYBEAN OIL (UNII: 241ATL177A)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				

Product Characteristics				
Color green Score no score				
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	CHBPN	
Contains	Contains			

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		2 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	07/01/2020				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/01/2020	

## Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2023 Bayer HealthCare LLC.