#### CORICIDIN HBP MAXIMUM STRENGTH COLD AND FLU DAY AND NIGHTacetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate Bayer HealthCare LLC.

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Coricidin HBP Maximum Strength Cold & Flu Day & Night Liquidgels Coricidin HBP® Maximum Strength Cold & Flu Day Liquid Gels

#### Active ingredients

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

| Acetaminophen 325 mg | Pain reliever/fever reducer |
|----------------------|-----------------------------|
| Guaifenesin 200 mg   | Expectorant                 |

#### Purpose

#### Uses

#### Uses

- $\cdot$  temporarily relieves these symptoms due to a cold or flu:
- $\cdot$  minor aches and pains  $\cdot$  headache
- sore throat
- $\cdot$  helps loosen phlegm (mucus) and thin bronchial secretions to make

coughs 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:

 $\cdot$  skin reddening  $\cdot$  blisters  $\cdot$  rash  $\cdot$  hives

 $\cdot$  facial swelling  $\cdot$  asthma (wheezing)  $\cdot$  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 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, chronic bronchitis,

or emphysema

cough that occurs with excess phelgm

## 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

- $\cdot$  pain or cough gets worse or lasts more than 7 days
- $\cdot$  fever gets worse or lasts more than 3 days
- $\cdot$  redness or swelling is present
- $\cdot$  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

 $\cdot$  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.

 $\cdot$  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.

 $\cdot$  children under 12 years of age: do not use

#### Other information

#### Other information

store at 15º-25ºC (59º-77ºF)

#### **Inactive ingrediens**

*Inactive ingredients*FD&C Yellow#6, gelatin, glycerin, iron oxide black, lecithin, medium-chain triglycerides, mica, 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 Stregth Cold & Flu Night Liquid Gels

#### 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

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains  $\cdot$  headache  $\cdot$  cough
- sore throat · runny nose · sneezing
- temporarily reduces fever

#### **Liver Warning**

**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

 $\cdot$  facial swelling  $\cdot$  asthma (wheezing)  $\cdot$  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 before use if you have

● liver disease ● glaucoma

• persistent or chronic cough such as occurs with smoking, asthma,

or emphysema

- cough that occurs 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

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

#### 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

- $\cdot$  pain or cough gets worse or lasts more than 7 days
- · fever gets worse or lasts more than 3 days
- $\cdot$  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, 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

 $\cdot$  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 Day dose before taking the Night product.

 $\cdot$  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.

 $\cdot$  children under 12 years of age: do not use

## Other information

store at 15º-25ºC (59º-77ºF)

**Inactive ingredients** D&C yellow No.10, FD&C blue No.1, gelatin, glycerin, lecithin, medium-chain triglycerides, silica, polyethylene glycol, potassium aluminum silicate,

povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, soybean oil, titanium dioxide

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

## Coricidin® HBP Maximum Strength Cold & Flu Liquid Gels



Coricidin® HBP

## COLD RELIEF FOR PEOPLE WITH HIGH BLOOD PRESSURE

## MAXIMUM STRENGTH

## COLD & FLU DAY

## ACETAMINOPHEN - Pain Reliever/Fever Reducer

## **GUAIFENESIN - Expectorant**

#### Relieves

- Body Aches & Pains
- Headache
- Chest Congestion
- Sore Throat
- Fever

## + Decongestant Free

16 LIQUID GELS

(Liquid Filled Capsules)

## COLD & FLU NIGHT

#### **DOXYLAMINE SUCCINATE - Antihistamine**

#### **ACETAMINOPHEN - Pain Reliever/Fever Reducer**

#### **DEXTROMETHORPHAN HBr- Cough Suppressant**

#### 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

| Ρ  | Product Information     |             |                 |         |                   |                        |            |                        |     |                       |  |
|----|-------------------------|-------------|-----------------|---------|-------------------|------------------------|------------|------------------------|-----|-----------------------|--|
| Ρ  | roduc                   | t Type      |                 | HUMAN ( | DTC DRUG          | H                      | tem Code ( | (Source)               | NDC | :11523-0100           |  |
|    |                         |             |                 |         |                   |                        |            |                        |     |                       |  |
|    | -                       |             |                 |         |                   |                        |            |                        |     |                       |  |
| P  | acka                    | ging        |                 |         |                   |                        |            |                        |     |                       |  |
| #  | lter                    | n Code      |                 | Pa      | ckage Descrip     | tio                    | n          | Marketing Star<br>Date | t   | Marketing End<br>Date |  |
| 1  | NDC:1<br>0100-          | L1523-<br>1 | 1 in 1<br>Produ |         | PACK; Type 0: Not | a C                    | ombination | 07/01/2022             |     |                       |  |
|    |                         |             |                 |         |                   |                        |            |                        |     |                       |  |
| Q  | uant                    | ity of P    | arts            |         |                   |                        |            |                        |     |                       |  |
| Pa | Part # Package Quantity |             |                 |         |                   | Total Product Quantity |            |                        |     |                       |  |
|    | art 1 4 BLISTER PACK    |             |                 |         |                   | 8                      |            |                        |     |                       |  |
| Pa | art 2                   | 2 BLISTER   | PACK            |         |                   |                        | 4          |                        |     |                       |  |
|    |                         |             |                 |         |                   |                        |            |                        |     |                       |  |
| D  | o rt                    | 1 of 2      |                 |         |                   |                        |            |                        |     |                       |  |
| r  | art                     | 1 01 2      |                 |         |                   |                        |            |                        |     |                       |  |
| С  | ORI                     | CIDIN       | HBF             | P MA)   |                   | RE                     | NGTH C     | COLD AND FL            | UC  | DAY                   |  |
| a  | cetam                   | ninophen    | , guait         | fenesin | capsule, liquid   | fille                  | d          |                        |     |                       |  |
|    |                         |             |                 |         |                   |                        |            |                        |     |                       |  |
| _  |                         |             |                 |         |                   |                        |            |                        |     |                       |  |
| Ρ  | rodu                    | ct Infor    | mati            | on      |                   |                        |            |                        |     |                       |  |
| R  | oute                    | of Admin    | istrat          | ion     | ORAL              |                        |            |                        |     |                       |  |
|    |                         |             |                 |         |                   |                        |            |                        |     |                       |  |
|    |                         |             |                 |         |                   |                        |            |                        |     |                       |  |

| Active Ing   | redient                                       | t/Active Moiet     | ÿ                         |         |                 |                     |         |                   |
|--|---|--------------------|---------------------------|---------|-----------------|---------------------|---------|-------------------|
|  |   | Ingredient         | Name                      |         |                 | Basis of S          | trength | Strength          |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209  |   |                    |                           |         |                 | L9D) ACETAMINOPHEN  |         | 325 mg            |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) |   |                    |                           |         |                 | GUAIFENESIN         |         | 200 mg            |
|  |   |                    |                           |         |                 |                     |         |                   |
| Incetive In  | ara dia                                       | nto                |                           |         |                 |                     |         |                   |
| Inactive In  | greale  |                    |                           |         |                 |                     | -       |                   |
|  | .1  | -                  | redient Name              | 3       |                 |                     | 5       | trength           |
| MICA (UNII: V8   |   | -                  |                           |         |                 |                     |         |                   |
|  |   | UNII: 1DI56QDM62)  |                           |         |                 |                     |         |                   |
| SHELLAC (UNII  |   |                    |                           |         |                 |                     |         |                   |
| SORBITOL (UN   |   |                    |                           |         |                 |                     |         |                   |
| WATER (UNII: (   |   | -                  |                           |         |                 |                     |         |                   |
|  |   | (UNII: 55X04QC32I) |                           |         |                 |                     |         |                   |
| SORBITAN (UN   |   |                    |                           |         |                 |                     |         |                   |
|  |   | DE (UNII: XMOM87F3 | (57)                      |         |                 |                     |         |                   |
|  |   | M DISILICATE (UN   |                           |         |                 |                     |         |                   |
|  |   |                    |                           |         |                 |                     |         |                   |
|  |   | (UNII: H77VEI93A8) |                           |         |                 |                     |         |                   |
|  |   | YCERIDES (UNII: C  | 9H2L21V7U)                |         |                 |                     |         |                   |
|  |   | (UNII: 6DC9Q167V3) |                           |         |                 |                     |         |                   |
|  |   | OL, UNSPECIFIED    |                           | VIA)    |                 |                     |         |                   |
| GELATIN (UNII:   |   |                    |                           |         |                 |                     |         |                   |
| GLYCERIN (UN   | II: PDC6A                                     | A3C0OX)            |                           |         |                 |                     |         |                   |
|  |   |                    |                           |         |                 |                     |         |                   |
|  |   |                    |                           |         |                 |                     |         |                   |
| <b>Product Ch</b>  | naracto                                       | eristics           |                           |         |                 |                     |         |                   |
| Color  |   | orange             |                           | Score   |                 |                     | no scor | e                 |
| Shape  |   | OVAL (oblong)      |                           | Size    |                 | 18mm                |         |                   |
| Flavor   |   |                    |                           | Imprint | print Code CHBP |                     |         |                   |
| Contains   |   |                    |                           | -       |                 |                     |         |                   |
|  |   |                    |                           |         |                 |                     |         |                   |
|  |   |                    |                           |         |                 |                     |         |                   |
| Packaging  |   |                    |                           |         |                 |                     |         |                   |
| # Item<br>Code   |   | Package D          | escription                |         |                 | ing Start<br>ate    |         | ting End<br>ate   |
| 1  | 2 in 1 BUSTER PACK: Type 0: Not a Combination |                    |                           |         |                 |                     |         |                   |
|  | ·····   |                    |                           |         |                 |                     |         |                   |
|  |   |                    |                           |         |                 |                     |         |                   |
| Marketir   | ng Inf  | formation          |                           |         |                 |                     |         |                   |
| Marketir<br>Categor  |   | Application Nu     | umber or Mono<br>Citation | ograph  |                 | eting Start<br>Date |         | eting End<br>Date |
| OTC Monograp   | h Drug  | M012               |                           |         | 07/01/20        | 20                  |         |                   |
|  |   |                    |                           |         |                 |                     |         |                   |
|  |   |                    |                           |         |                 |                     |         |                   |
| Part 2 of  | F 2   |                    |                           |         |                 |                     |         |                   |
|  |   |                    |                           |         |                 |                     |         |                   |

## CORICIDIN HBP MAXIMUM STRENGTH COLD AND FLU NIGHT

acetaminophen, doxylamine succinate, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

| Product Information                             | n              |                                |                                 |       |         |
|---|----------------|--------------------------------|---------------------------------|-------|---------|
| Route of Administratio                          | n ORAL         |                                |                                 |       |         |
|   |                |                                |                                 |       |         |
| Active Ingredient/Ac                            | tive Moiet     | ty                             |                                 |       |         |
| I   | ngredient      | Name                           | Basis of Stre                   | ngth  | Strengt |
| DOXYLAMINE SUCCINATE<br>JNII:95QB77JKPL)        | (UNII: V9BI9B5 | YI2) (DOXYLAMINE -             | DOXYLAMINE SUCC                 | INATE | 6.25 mg |
| ACETAMINOPHEN (UNII: 36                         | 209ITL9D) (AC  | ETAMINOPHEN - UNII:36209ITL9D) | ACETAMINOPHEN                   |       | 325 mg  |
| DEXTROMETHORPHAN HY<br>(DEXTROMETHORPHAN - UNII |                |                                | DEXTROMETHORPH,<br>HYDROBROMIDE | AN    | 10 mg   |
| Inactive Ingredients                            |                |                                |                                 |       |         |
| indetive ingredients                            |                | redient Name                   |                                 | St    | trength |
| LECITHIN, SOYBEAN (UNII:                        | 1DI56QDM62)    |                                |                                 |       | -       |
| SHELLAC (UNII: 46N107B71                        | O)             |                                |                                 |       |         |
| SORBITAN (UNII: 6092ICV9F                       | RU)            |                                |                                 |       |         |
| MEDIUM-CHAIN TRIGLYCE                           | RIDES (UNII: C | C9H2L21V7U)                    |                                 |       |         |
| POVIDONE (UNII: FZ989GH9                        | 94E)           |                                |                                 |       |         |
| SODIUM HYDROXIDE (UNII:                         | 55X04QC32I)    |                                |                                 |       |         |
| SORBITOL (UNII: 506T60A2                        | 5R)            |                                |                                 |       |         |
| SOYBEAN OIL (UNII: 241ATI                       | _177A)         |                                |                                 |       |         |
| TITANIUM DIOXIDE (UNII: 1                       |                |                                |                                 |       |         |
| PROPYLENE GLYCOL (UNII:                         |                | )                              |                                 |       |         |
| WATER (UNII: 059QF0KO0R)                        |                |                                |                                 |       |         |
| FD&C BLUE NO. 1 (UNII: H                        |                |                                |                                 |       |         |
| POLYETHYLENE GLYCOL,                            |                |                                |                                 |       |         |
| D&C YELLOW NO. 10 (UNII                         |                | 6)                             |                                 |       |         |
| GELATIN (UNII: 2G86QN327                        |                |                                |                                 |       |         |
| GLYCERIN (UNII: PDC6A3C0                        | JX)            |                                |                                 |       |         |
|   |                |                                |                                 |       |         |
| Product Characteris                             | tics           |                                |                                 |       |         |
| Color   | green          | Score                          | no                              | score |         |
| Shape   | OVAL           | Size                           | 17r                             | nm    |         |
| Flavor  |                | Imprint Code                   | CHI                             | BPN   |         |
| Contains  |                |                                |                                 |       |         |
| Dackaging                                       |                |                                |                                 |       |         |
| Packaging                                       |                |                                |                                 |       |         |

| #   | Code                 |                  | Package Description                         | Date                    | Date                  |
|-----|----------------------|------------------|---|-------------------------|-----------------------|
| 1   |                      | 2 in 1<br>Produc | BLISTER PACK; Type 0: Not a Combination     |                         |                       |
|     |                      |                  |   |                         |                       |
| Ma  | arketin              | g In             | formation                                   |                         |                       |
|     | Marketin<br>Category | -                | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| ото | C Monograph          | n Drug           | M012  | 07/01/2020              |                       |
| M   | arketin              | a In             | formation                                   |                         |                       |
|     | Marketin             | •                | Application Number or Monograph             | Marketing Start         | Marketing End         |
|     | Category             | -                | Citation                                    | Date                    | Date                  |
| ото | C Monograph          | Drug             | M012  | 07/01/2020              |                       |
|     |                      |                  |   |                         |                       |

## Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2023

Bayer HealthCare LLC.