

The following statement should appear above the Drug Facts box: Do not take these products at the same time.

The product name should appear outside the Drug Facts box: Coricidin HBP® Maximum Strength Cold & Flu Day Liquid Gels

# **Drug Facts**

Active ingredients (in each capsule)

**Purposes** 

Acetaminophen 325 mg......Pain reliever/fever reducer Guaifenesin 200 mg.....

..Expectorant

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

- 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

# 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 is accompanied by excessive phlegm (mucus)

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 the recommended dose
- 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

• store at 15°-25°C (59°-77°F)

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



The product name should appear outside the Drug Facts box: Coricidin® HBP Maximum Strength Cold & Flu Night Liquid Gels

# **Drug Facts**

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

- 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 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

- 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 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

• store at 15°-25°C (59°-77°F)

**Inactive ingredients** D&C yellow No.10, FD&C blue No.1, gelatin, glycerin, lecithin, medium-chain triglycerides, 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)



# **PDP Statement of Identity**

Coricidin® HBP Maximum Strength Cold & Flu Day Liquid Gels:

**Acetaminophen** / Pain reliever-fever reducer Guaifenesin /Expectorant

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

**Acetaminophen** / Pain Reliever-Fever Reducer Dextromethorphan Hydrobromide / Cough Suppressant Doxylamine Succinate / Antihistamine

Abbreviations can be used if space constraints on PDP to read as below:

**Acetaminophen** / Pain Reliever-Fever Reducer Dextromethorphan HBr / Cough Suppressant Doxylamine Succinate / Antihistamine

# **Contact Information-Preferred format:**

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

If there are space constrains, the following abbreviated formats may be used.

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

Or

Questions? 1-800-317-2165

The following statement must appear prominently on outer carton and in bold type:

**Maximum Strength Per 4 Hour Dose**