

## **CHERACOL D COUGH FORMULA 4OZ- maximum strength cough relief syrup**

**Lee Pharmaceuticals**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **▯Drug Facts**

#### **Active ingredients ▯(5 mL teaspoonful)**

Dextromethorphan HBr, 10mg

Guaifenesin, 100mg

### **▯Purpose**

Cough suppressant

Expectorant

### **▯Uses**

- Temporarily quiets coughs due to minor throat and bronchial irritation associated with the common cold.
- Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.

### **▯Warnings**

#### **Do not use**

- ▯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're uncertain whether your prescription drug contains MAOI, ask a doctor or pharmacist before taking this product.

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

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

#### **▯Stop use and ask a doctor if**

- cough persists for more than one week
- cough tends to recur or is accompanied by fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.

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

**▯Keep out of reach of children.**▯ In case of accidental overdose, get medical help or contact a Poison Control Center immediately.

### **▯Directions**

- Follow dosage below or use as directed by a doctor
- Do not exceed 6 dosages in 24 hours
- Adults and children 12 years or age and over, 2 teaspoonfuls every 4 hours

- Children 6 to under 12 years of age, 1 teaspoonful every 4 hours
- Children under 6 years of age, consult a doctor

### Other information

Store from 15° - 30°C (59° - 86°F)

### ☐Inactive ingredients

Alcohol 4.75%, benzoic acid, FD&C red #40, flavors, fructose, glycerin, propylene glycol, sodium chloride, sucrose, water.

### ☐Questions or Comments

- 1-800-950-5337, M-F, 9am-4pm, PST
- Visit our website at: [www.lee pharmaceuticals.com](http://www.lee pharmaceuticals.com)

Do not use if printed band around bottle cap  
is broken or missing

# Cheracol D<sup>®</sup>

## COUGH FORMULA

### Maximum Strength Cough Relief

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**Strong enough for adults, safe  
for children 6 years and over**

**Contains 4.75% Alcohol**

Helps Quiet  
Dry, Hacking Coughs

Helps Loosen  
Phlegm and Mucus

Helps Drain  
Bronchial Tubes

4 FL OZ

Rev. 4/99  
1698370


NDC 23558-5504-0

### 4 Fl Oz Cheracol D<sup>®</sup>

**Dosage — Adults and children 12 years of age and over:** Oral dosage is 2 teaspoonfuls every 4 hours, not to exceed 12 teaspoonfuls in 24 hours, or as directed by a doctor. **Children 6 to under 12 years of age:** Oral dosage is 1 teaspoonful every 4 hours, not to exceed 6 teaspoonfuls in 24 hours, or as directed by a doctor. **Children under 6 years of age:** Consult a doctor. **Warnings:** Keep this and all medication out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. Do not give this product to children under 6 years except under the advice and supervision of a physician. Do not take this product for a persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or where cough is accompanied by excessive secretions except under the advice and supervision of a physician. As with any drug, pregnant or nursing women should seek the advice of a health professional before using this product. **Drug Interaction Precaution:** Do not use this product 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 are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product. **Caution—**A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur or is accompanied by high fever, rash or persistent headache, consult a physician. **Active Ingredients:** Each teaspoonful (5 ml) contains Dextromethorphan hydrobromide, 10 mg; guaifenesin, 100 mg. **Inactive Ingredients:** alcohol 4.75%, benzoic acid, FD & C Red #40, flavors, fragrances, fructose, glycerin, propylene glycol, sodium chloride, sucrose, and purified water. Store from 15° - 30°C (59° - 86°F).

Distributed by: Lee Pharmaceuticals  
South El Monte, CA. 91733  
Questions? (800) 950-5337

Rev. 4/99  
1698450



0 23558 55040 7

NDC 23558-5504-0

**Maximum Strength**

# Cheracol D<sup>®</sup> COUGH FORMULA

### Drug Facts

**Active Ingredients (5 ml tspful) Purpose**  
Dextromethorphan HBr, 10 mg ..... Cough suppressant  
Guaifenesin, 100 mg ..... Expectorant

### Uses

- Temporarily quiets coughs due to minor throat and bronchial irritation associated with the common cold.
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0 23558 55040 7

### Drug Facts (continued)

#### Directions

- Follow dosage below or use as directed by a doctor
- Do not exceed 6 dosages in 24 hours

Adults and children 12 years of age and over	2 teaspoonfuls every 4 hours
Children 6 to under 12 years of age	1 teaspoonful every 4 hours
Children under 6 years of age	Consult a doctor

#### Other information

Store from 15°-30C° (59°-86°F)

#### Inactive Ingredients:

Alcohol 4.75%, benzoic acid, FD&C red # 40, flavors, fructose, glycerin, propylene glycol, sodium chloride, sucrose, water.

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**Cheracol D<sup>®</sup>**  
**Maximum Strength**  
**COUGH FORMULA**

Do not use if printed band around bottle cap is broken or missing

NDC 23558-5504-0

# Cheracol D<sup>®</sup> COUGH FORMULA

**Maximum Strength Cough Relief**

## Cheracol D<sup>®</sup>

can be used by everyone in the family 6 years and over for the temporary relief of coughs due to the common cold.

- Helps quiet dry hacking coughs
- Helps loosen phlegm, mucus and bronchial secretions

Strong enough for adults, safe for children 6 years and over  
Contains 4.75% Alcohol

## Cheracol D<sup>®</sup> COUGH FORMULA

**Maximum strength relief for coughs due to the common cold.**

**Helps Quiet Dry, Hacking Coughs**  
**Helps Loosen Phlegm and Mucus**

**Helps Drain Bronchial Tubes**

**4 FL OZ (118 mL)**

**Maximum strength relief for coughs due to the common cold.**

Manufactured by:  
**LEE PHARMACEUTICALS**  
South El Monte, CA 91733

159837C  
Rev. 12/11

Do not use if printed band around bottle cap  
is broken or missing

# **Cheracol D<sup>®</sup>**

## **COUGH FORMULA**

### **Maximum Strength Cough Relief**

**Strong enough for adults, safe  
for children 6 years and over**  
**Contains 4.75% Alcohol**

**Helps Quiet  
Dry, Hacking Coughs**

**Helps Loosen  
Phlegm and Mucus**

**Helps Drain  
Bronchial Tubes**

**6 FL OZ**

Rev. 4/99  
1698380

NDC 23558-5504-2

## **6 Fl Oz Cheracol D<sup>®</sup>**

**Dosage** — Adults and children 12 years of age and over: Oral dosage is 2 teaspoonfuls every 4 hours, not to exceed 12 teaspoonfuls in 24 hours, or as directed by a doctor. **Children 6 to under 12 years of age:** Oral dosage is 1 teaspoonful every 4 hours, not to exceed 6 teaspoonfuls in 24 hours, or as directed by a doctor. **Children under 6 years of age:** Consult a doctor. **Warnings:** Keep this and all medication out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. Do not give this product to children under 6 years except under the advice and supervision of a physician. Do not take this product for a persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or where cough is accompanied by excessive secretions except under the advice and supervision of a physician. As with any drug, pregnant or nursing women should seek the advice of a health professional before using this product. **Drug Interaction Precaution:** Do not use this product 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 are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product. **Caution**—A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur or is accompanied by high fever, rash or persistent headache, consult a physician. **Active Ingredients:** Each teaspoonful (5 ml) contains Dextromethorphan hydrobromide, 10 mg; guaifenesin, 100 mg. **Inactive Ingredients:** alcohol 4.75%, benzoic acid, FD & C Red #40, flavors, fragrances, fructose, glycerin, propylene glycol, sodium chloride, sucrose, and purified water. Store from 15° - 30°C (59° - 86°F).

Distributed by: Lee Pharmaceuticals  
South El Monte, CA. 91733  
Questions? (800) 950-5337

1698520  
Rev. 4/99



**Cheracol D<sup>®</sup>**  
Maximum Strength  
COUGH FORMULA

NDC 23558-5504-2

**Maximum Strength**

**Cheracol D<sup>®</sup>**  
**COUGH FORMULA**

**Drug Facts**

**Active Ingredients (5 ml teaspoonful) Purpose**  
Dextromethorphan HBr, 10 mg..... Cough suppressant  
Guaifenesin, 100 mg..... Expectorant

**Uses**

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**Drug Facts** (continued)

**Directions**

- Follow dosage below or use as directed by a doctor
- Do not exceed 6 dosages in 24 hours

Adults and children 12 years of age and over	2 teaspoonfuls every 4 hours
Children 6 to under 12 years of age	1 teaspoonful every 4 hours
Children under 6 years of age	Consult a doctor

**Other information**

Store from 15°-30°C (59°-86°F).

**Inactive Ingredients:**

Alcohol 4.75%, benzoic acid, FD&C red #40, flavors, fragrances, fructose, glycerin, propylene glycol, sodium chloride, sucrose, water.

**Questions or Comments**

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NDC 23558-5504-2

**Cheracol D<sup>®</sup>**  
**COUGH FORMULA**

**Maximum Strength Cough Relief**

Strong enough for adults, safe for children 6 years and over  
Contains 4.75% Alcohol

**Cheracol D<sup>®</sup>**

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**COUGH FORMULA**

**Maximum strength relief for coughs due to the common cold.**

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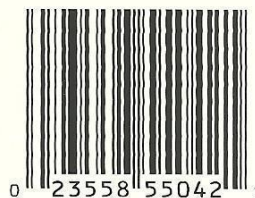
**Helps Drain Bronchial Tubes**

Manufactured by:  
LEE PHARMACEUTICALS  
South El Monte, CA 91733

159838A  
Rev. 3/02

6 FL OZ

**Maximum strength relief for coughs due to the common cold.**



**CHERACOL D COUGH FORMULA 4OZ**

maximum strength cough relief syrup

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:23558-5504
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FRUCTOSE</b> (UNII: 6YSS42VSEV)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23558-5504-0	1 in 1 CARTON		
1	NDC:23558-5504-1	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:23558-5504-2	1 in 1 CARTON		
2	NDC:23558-5504-3	177 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/01/2011	

**Labeler** - Lee Pharmaceuticals (056425432)

**Registrant** - Lee Pharmaceuticals (056425432)

### Establishment

Name	Address	ID/FEI	Business Operations
Lee Pharmaceuticals		056425432	manufacture(23558-5504)