

# **COUGH AND COLD- chlorpheniramine maleate, dextromethorphan hbr tablet, film coated**

## **Major Pharmaceuticals**

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### **Major 44-689**

#### ***Active ingredients (in each tablet)***

Chlorpheniramine maleate 4 mg

Dextromethorphan HBr 30 mg

#### ***Purpose***

Antihistamine

Cough suppressant

#### ***Uses***

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves runny nose and sneezing due to the common cold

#### ***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 do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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

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

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

taking sedatives or tranquilizers.

##### **When using this product**

- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages

- use caution when driving a motor vehicle or operating machinery

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

cough persists more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. 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.

### ***Directions***

- **do not take more than directed**
- adults and children 12 years and over: 1 tablet every 6 hours, not more than 4 tablets in 24 hours
- children under 12 years: do not use

### ***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

croscarmellose sodium, D&C red #27 aluminum lake, FD&C yellow #6 aluminum lake, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

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

**1-800-426-9391**

### **Principal Display Panel**

**MAJOR®**

NDC 0904-6634-44

compare to the active ingredients in  
Coricidin® HBP COUGH & COLD\*

**cough & cold**

**HBP**

**chlorpheniramine maleate 4 mg**

antihistamine

**dextromethorphan HBr 30 mg**

cough suppressant

relieves: cough, runny nose, sneezing

- for people with high blood pressure
- decongestant free

actual size

**16 tablets**

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

**PARENTS:**

**Learn about teen medicine abuse**

**[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)**

\*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Coricidin® HBP COUGH & COLD.

50844 REV0224C68921

Distributed by:

**MAJOR® PHARMACEUTICALS**

Indianapolis, IN 46268

**(800) 616-2471**

[www.major-rugby.com](http://www.major-rugby.com)

**MAJOR** NDC 0904-6634-44  
**cough & cold HBP**

**MAJOR** NDC 0904-6634-44  
 compare to the active ingredients in Coricidin<sup>®</sup> HBP COUGH & COLD<sup>®</sup>

**cough & cold HBP**

**chlorpheniramine maleate 4 mg** antihistamine  
**dextromethorphan HBr 30 mg** cough suppressant

relieves: cough, runny nose, sneezing

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- decongestant free

**16 tablets**

actual size

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No Print/No Varnish Lot & EXP

Rev. 10/25 M17 Re-order No. 700844  
 3 09046 6344 7

8-1212-689-21-R1  
 REV0224C68921

**Drug Facts** KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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 Dextromethorphan HBr 30 mg.....Cough suppressant

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**Major 44-689**

## COUGH AND COLD

chlorpheniramine maleate, dextromethorphan hbr tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6634
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 27 ALUMINUM LAKE</b> (UNII: ZK64F7XSTX)	

<b>FD&amp;C YELLOW NO. 6 ALUMINUM LAKE</b> (UNII: GYP6Z2JR6Q)	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	44;689
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6634-44	2 in 1 CARTON	03/31/2017	
1		8 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	03/31/2017	

**Labeler** - Major Pharmaceuticals (191427277)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-6634) , pack(0904-6634)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0904-6634)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0904-6634)

