

**COUGH AND COLD- chlorpheniramine maleate, dextromethorphan hbr tablet, sugar coated  
Proficient Rx LP**

*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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**Major 44-411**

***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**

- trouble urinating due to an enlarged prostate gland
- glaucoma
- cough that occurs with excessive phlegm (mucus)
- a breathing problem or persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, 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
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness

- use caution when driving a motor vehicle or operating machinery

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

persistent cough lasts for more than one week, tends to recur, or is accompanied by 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 (1-800-222-1222) right away.

### **Directions**

- **do not exceed recommended dose**
- adults and children 12 years and over: 1 tablet every 6 hours. Do not take 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°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### **Inactive ingredients**

acacia, black iron oxide, calcium carbonate, carnauba wax, croscarmellose sodium, D&C red #27 aluminum lake, FD&C yellow #6 aluminum lake, lactose, magnesium stearate, methylparaben, microcrystalline cellulose, povidone, propylparaben, propylene glycol, shellac, silica gel, sodium benzoate, stearic acid, sugar, talc, titanium dioxide

### **Questions or comments?**

**(800) 616-2471**

### **Principal Display Panel**

**MAJOR®**

NDC 63187-689-16

**\*Compare to the active ingredients in Coricidin® HBP Cough & Cold**

### **Cough & Cold**

**Relief for people with High Blood Pressure**

Chlorpheniramine maleate - Antihistamine

Dextromethorphan HBr - Cough Suppressant

### **Decongestant Free**

Relieves

• Cough • Runny Nose • Sneezing

16 TABLETS

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

\*This product is not manufactured or distributed by MSD Consumer Care, Inc., owner of the registered trademark Coricidin® HBP Cough & Cold.

50844 REV0714D41121

Distributed by **MAJOR® PHARMACEUTICALS**



31778 Enterprise Drive, Livonia, MI 48150 USA M-17

Re-order No. 873602

Rev. 08/14

Relabeled By: Proficient Rx LP

Thousand Oaks, CA 91320

NDC 63187-689-16

Lot #:00000  
Exp. 00/00/00  
SN# MASTER

## Cough & Cold

### #16 Tablets

Each tablet contains: Chlorpheniramine maleate 4mg  
Antihistamine / Dextromethorphan HBr 30mg Cough  
Suppressant

*Round, red, unscored tablet with imprint code "411"*

Product ID: RC068916

Dist. By: MAJOR PHARMACEUTICALS 31778 Enterprise Drive, Livonia, MI 48150 USA

Store at 25°C (77°F) Keep medication out of the reach of children

Cough & Cold #16 Tablets Lot #:00000 NDC 63187-689-16	SN#MASTER Exp:00/00/00
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Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

**Major 44-411**

## COUGH AND COLD

chlorpheniramine maleate, dextromethorphan hbr tablet, sugar coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63187-689(NDC:0904-5817)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	411
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-689-16	2 in 1 CARTON	04/01/2016	
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 final	part341	05/03/2003	

**Labeler** - Proficient Rx LP (079196022)

## Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079502574	RELABEL(63187-689)