

**RESCON- dexchlorpheniramine maleate and pseudoephedrine hydrochloride tablet, multilayer**  
**Capellon Pharmaceuticals, LLC**

*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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**RESCON® Tablets**

***Drug Facts***

***Active Ingredients (per tablet)***

Dexchlorpheniramine Maleate 2 mg

Pseudoephedrine Hydrochloride 60 mg

***Purpose***

Dexchlorpheniramine Maleate Antihistamine

Pseudoephedrine Hydrochloride Nasal Decongestant

***Uses***

For the temporary relief of

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever or other upper respiratory allergies
- nasal congestion

Temporarily helps

- clear nasal passages
- shrink swollen membranes

***Warnings***

- **Do not exceed recommended dosage**
- **May cause excitability especially in children**
- May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect.

***When using this product***

- Avoid alcoholic beverages

- Use caution when driving a motor vehicle or operating machinery.

### **Do not use**

- If you have a breathing problem such as emphysema or chronic bronchitis
- 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

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

- If nervousness, dizziness, or sleeplessness occur.
- If symptoms do not improve within 7 days or are accompanied by fever.

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

- glaucoma
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- or if you are taking sedatives or tranquilizers

### **If pregnant or breast feeding**

Ask a health professional before use.

### **Keep out of the reach of children**

In case of accidental overdose, seek professional help or contact a Poison Control Center immediately.

### ***Directions***

- **Adults (12 and older):** One tablet every 4 to 6 hours. Not to exceed 4 doses in 24 hours.
- **Children under 12 years of age:** Consult a physician.

### ***Other information***

store at 20°-25°C (68°-77°F)

### ***Inactive ingredient***

colloidal silicon dioxide, crospovidone polyplasdone, D&C Red #30, D&C Yellow #10, FD&C Blue #1, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and povidone

## Questions or Comments?

Serious side effects may be reported to this number, call (817) 595-5820. (8 am to 5)

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1: 90 ct product label



## RESCON

dexchlorpheniramine maleate and pseudoephedrine hydrochloride tablet, multilayer

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64543-097
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXCHLORPHENIRAMINE MALEATE</b> (UNII: B10YD955QW) (DEXCHLORPHENIRAMINE - UNII:3Q9Q0B929N)	DEXCHLORPHENIRAMINE MALEATE	2 mg
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	

**Product Characteristics**

<b>Color</b>	yellow, purple	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	RES11
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64543-097-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2012	
2	NDC:64543-097-02	1 in 1 POUCH; Type 0: Not a Combination Product	03/30/2012	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/30/2012	

**Labeler** - Capellon Pharmaceuticals, LLC (124568093)

Revised: 11/2022

Capellon Pharmaceuticals, LLC