# TUSSIN MULTI SYMPTOM COLD CF ADULT- dextromethorphan hbr, guaifenesin, phenylephrine liquid Preferred Pharmaceuticals Inc.

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 (in each 10 mL)

Dextromethorphan HBr 20 mg
Guaifenesin 200 mg
Phenylephrine HCl 10 mg

### **Purposes**

Cough suppressant

Expectorant

Nasal decongestant

#### Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
  - nasal congestion
  - cough due to minor throat and bronchial irritation

## 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

- heart disease
- high blood pressure
- diabetes

- thyroid
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm ( mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

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

taking any other oral nasal decongestant or stimulant.

# When using this product, do not use more than directed.

## Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, 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 (1800-222-1222) right away.

#### **Directions**

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL = milliliter
- this adult product is not intended for use in children under 12 years of age
- adult and children 12 years and over: 10 mL every 4 hours
- children under 12 years: do not use

#### Other information

• store between 20-25°C (68°-77°F). Do not refrigerate.

## **Inactive ingredients**

anhydrous citric acid, FD&C red #40, flavor, glycerin, lactic acid, menthol, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose

#### Questions or comments?

### Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

## **Principal Display Panel**

**ROBAFEN** 

#### CF MULTI-SYMPTOM COLD

Dextromethorphan HBr, 20 mg / COUGH SUPPRESSANT

Guaifenesin, 200 mg / EXPECTORANT

Phenylephrine HCl, 10 mg / NASAL DECONGESTANT

#### **PEAK COLD**

#### Relieves:

- Cough
- Mucus
- Nasal Congestion

Non-Drowsy

COMPARE TO the active ingredients in ROBITUSSIN® PEAK COLD MULTI-SYMPTOM COLD CF\*

FOR ADULTS

For Ages 12 Years and Over

Alcohol-Free

FL OZ (mL)

Dosing Cup Included

\*This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of Robitussin® Peak Cold Multi-Symptom Cold CF.

## TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

## KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

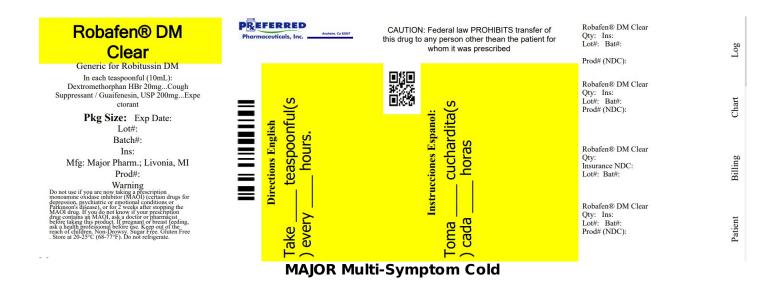
Distributed by:

MAJOR PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

## Package Label



Repackaged By: Preferred Pharmaceuticals Inc.

## TUSSIN MULTI SYMPTOM COLD CF ADULT

dextromethorphan hbr, guaifenesin, phenylephrine liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8147(NDC:0904-6537)
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 10 mL	

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788- 8147-0	1 in 1 BOX	09/01/2022	
1		118 mL in 1 BOTTLE, PLASTIC; 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	09/01/2022		

## **Labeler -** Preferred Pharmaceuticals Inc. (791119022)

## **Registrant - Preferred Pharmaceuticals Inc. (791119022)**

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8147)	

Revised: 9/2023 Preferred Pharmaceuticals Inc.