

FATHER JOHNS COUGH MEDICINE PLUS- nasal decongestant liquid
Humco Holding Group, 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.

Private Label Father John's Medicine Plus

Each 30 mL (2 tablespoonfuls) contain:

Dextromethorphan HBr, 10mg

Phenylephrine HCl, 10mg

Chlorpheniramine Maleate, 4mg

Citric acid

FD&C Red #40

FD&C Blue #1

Glycerin

Purified water

Sodium benzoate

Sodium chloride

Sodium citrate

Sodium saccharin

Sucrose

DO NOT take more than 12 tablespoonfuls in 24 hours

Adults and Children 12 years and older: take 2 tablespoons every 4 hours

Children under 12 years old: ask a doctor

For temporarily relief of cough and allergy symptoms, including coughing, nasal congestion, and runny nose.

WARNINGS: Do not exceed recommended dosage

Cough Suppressant

Nasal Decongestant

Antihistamine

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.


Drug Facts (continued)
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 12 tablespoonfuls in 24 hours.

Adults and Children 12 years and older	take 2 tablespoons every 4 hours.
Children under 12 years old	ask a doctor,

Other information - contains no alcohol or other habit forming drugs • store in a cool place • Tamper evident: do not use if bottle safety seal is broken or missing.

Inactive Ingredients citric acid, FD&C Red #40, FD&C Blue #1, glycerin, purified water, sodium benzoate, sodium chloride, sodium citrate, sodium saccharin, sucrose.



FATHER
JOHN'S
MEDICINE
PLUS

FOR COLDS and ALLERGIES

Drug Facts

Active ingredients	Purpose
Each 30 mL (2 tablespoonfuls) contain:	
Dextromethorphan HBr, 10 mg.....	Cough suppressant
Phenylephrine HCl, 10 mg.....	Nasal Decongestant
Chlorpheniramine Maleate, 4 mg.....	Antihistamine

Use For temporary relief of cough and allergy symptoms, including coughing, nasal congestion and runny nose.

WARNINGS
Do not exceed recommended dosage

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 are uncertain whether your prescription contains an MAOI, consult a health professional before taking this product.

Ask a doctor before use if you have • a persistent or chronic cough such as occurs with smoking, asthma, emphysema • a cough accompanied by chronic phlegm (mucus) • heart disease • high blood pressure • thyroid disease • diabetes • glaucoma • a breathing problem such as emphysema or chronic bronchitis • trouble urinating due to an enlarged prostate gland

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 heavy machinery

Stop use and ask a doctor if: cough persists for more than one week • cough tends to recur • cough is accompanied by fever, rash or persistent headache. A persistent cough may be a sign of a serious condition. • nervousness, dizziness or sleeplessness occurs • symptoms do not improve within 7 days or are accompanied by a fever.

UV Omit area
1/2" high

Distributed by:
OAKHURST COMPANY
LEVITTOWN, NY 11756
www.oakhurstco.com
1-800-831-1135

4 Fl. Oz. 118 mL.

FATHER JOHNS COUGH MEDICINE PLUS

nasal decongestant liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0395-9127
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0K00R)	

SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0395-9127-94	1 in 1 CARTON	06/17/2019	
1		118 mL in 1 CONTAINER; 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	06/17/2019	

Labeler - Humco Holding Group, Inc (825672884)

Registrant - Humco Holding Group, Inc (825672884)

Establishment

Name	Address	ID/FEI	Business Operations
Humco Holding Group, Inc		825672884	label(0395-9127) , pack(0395-9127) , analysis(0395-9127) , manufacture(0395-9127)

Revised: 6/2020

Humco Holding Group, Inc