MAXIFED- guaifenesin and pseudoephedrine hydrochloride tablet
MCR American 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.

Maxifed

Drug Facts

Active Ingredients (in each immediate-release tablet)	***Purpose***
Guaifenesin 360 mg	Expectorant
Pseudoephedrine HCl 60 mg	Nasal Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other respiratory allergies:

- helps loosen phlegm and thin bronchial secretions to make coughs more productive
- nasal congestion
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

Warnings

- **Do not exceed recommended dosage.**
- a persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

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

- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or if cough is accompanied by excessive phlegm
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:	1 tablet by mouth every 4 hours, not to exceed 4 tablets in 24 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	½ tablet by mouth every 4 hours, not to exceed 2 tablets in 24 hours, or as directed by a doctor.
Children 2 to under 6 years of age	consult a doctor

Inactive ingredients

Magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

Call 1-352-754-8587

PRINCIPAL DISPLAY PANEL - 360 mg/60 mg Tablet Bottle Label

NDC 58605-101-01
100 tablets

Maxifed

Expectorant • Nasal Decongestant

Each immediate-release tablet contains:
Guaifenesin 360 mg
Pseudoephedrine HCl 60 mg

Store at 59°-86°F (15°-30°C) [see USP Controlled Room Temperature].

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Lot :
Exp. Date:

100 tablets

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Lift Here

Drug Facts (continued)

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Rev. 01/18

Manufactured for:
MCR American Pharmaceuticals, Inc.
Brooksville, FL 34604

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58605-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	360 mg
Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Magnesium Stearate (UNII: 70097M6I30)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	MAXIFED
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58605-101-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2018	
2	NDC:58605-101-20	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2018	

Labeler - MCR American Pharmaceuticals, Inc. (783383011)

Establishment

Name	Address	ID/FEI	Business Operations
MCR American Pharmaceuticals, Inc.		783383011	MANUFACTURE(58605-101)

Revised: 3/2018 MCR American Pharmaceuticals, Inc.