MAXICHLOR PEH DM- chlorpheniramine maleate, dextromethorphan hydrobromide, and phenylephrine 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.

Maxichlor PEH DM

Drug Facts

Active Ingredients (in each tablet)	*Purpose*
Chlorpheniramine Maleate 4 mg	Antihistamine
Dextromethorphan HBr 18 mg	Cough Suppressant
Phenylephrine HCl 10mg	Nasal Decongestant

Uses

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

- cough due to minor throat and bronchial irritation associated with a cold
- alleviates cough to help you sleep
- non narcotic cough suppressant for relief of cough
- itchy, watery eyes
- nasal congestion
- runny nose
- sneezing
- itching of the nose and throat

Warnings

- **Do not exceed recommended dosage.**
- a persistent cough may be a sign of a serious condition.

Do not use this product

- If you are taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for two weeks after stopping the MAOI drug. If you do not know if your prescription drug contains 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 where cough is accompanied by excessive phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor before use if you are taking sedatives or tranquilizers

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. These could be signs of a serious condition.
- new symptoms 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 6 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 3 tablets in 24 hours, or as directed by a doctor
Children under 6 years of age:	Consult a doctor.

Inactive ingredients

Magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or Comments?

Call (352)754-8587

PRINCIPAL DISPLAY PANEL - 4 mg/18 mg/10 mg Tablet Bottle Label

NDC 58605-103-01
100 Tablets

Maxichlor PEH DM

Antihistamine • Cough Suppressant

Nasal Decongestant

Each tablet contains:
Chlorpheniramine Maleate 4 mg
Dextromethorphan HBr 18 mg
Phenylephrine HCl 10 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.

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Exp. Date:

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Call (352) 754-8587

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

Rev. 02/18

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58605-103
Route of Administration	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	18 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 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**	MAXICHLOR;PEH;DM
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58605-103-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2018	
2	NDC:58605-103-20	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(58605-103)

Revised: 3/2018 MCR American Pharmaceuticals, Inc.