GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE- guaifenesin and pseudoephedrine hydrochloride tablet, extended release
OHM LABORATORIES INC

Guaifenesin and Pseudoephedrine Hydrochloride

Drug Facts

Active ingredients (in each extended-release tablet)	*Purposes*
Guaifenesin 600 mg	Expectorant
Pseudoephedrine HCl 60 mg	Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
    - common cold
    - hay fever
    - upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

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
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

When using this product

- do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a fever, rash, or persistent headache. These could be signs of a serious illness.

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 (1-800-222-1222).

Directions

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: 2 tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- **Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing.**
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Questions?

(1-800-406-7984)

You may also report side effects to this phone number.

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

PRINCIPAL DISPLAY PANEL - 600 mg/60 mg Tablet Blister Pack Carton

†Compare To
the active ingredients of
Mucinex® D

NDC 51660-071-36

ohm®

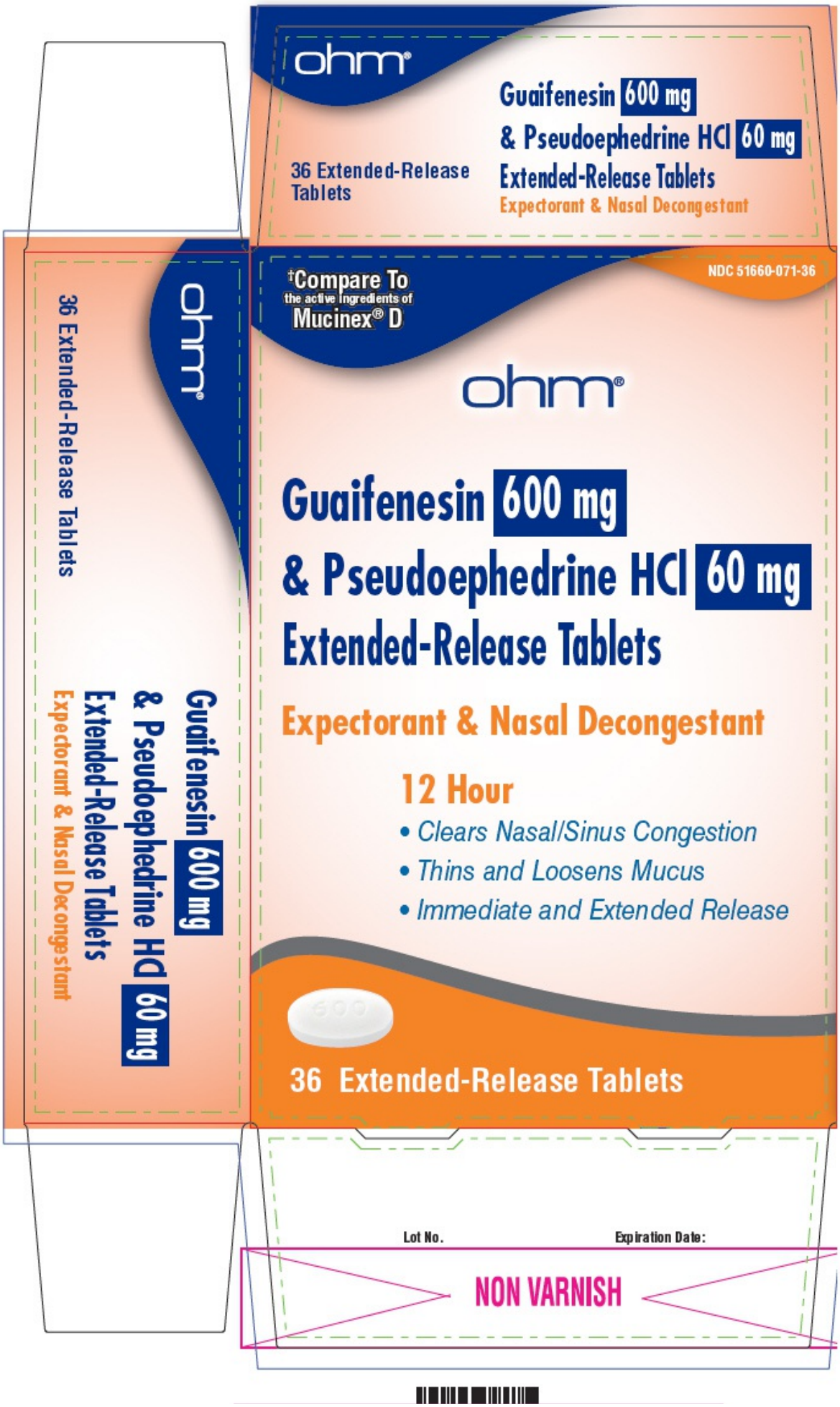
Guaifenesin 600 mg
& Pseudoephedrine HCl 60 mg
Extended-Release Tablets

Expectorant & Nasal Decongestant

12 Hour

- Clears Nasal/Sinus Congestion
- Thins and Loosens Mucus
- Immediate and Extended Release

36 Extended-Release Tablets


ohm
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600
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ohm
36 Extended-Release Tablets
Guaifenesin 600 mg
& Pseudoephedrine HCl 60 mg
Extended-Release Tablets
Expectorant & Nasal Decongestant
Lot No.
Expiration Date:
NON VARNISH

5188213

ohm®

Guaifenesin 600 mg & Pseudoephedrine HCl 60 mg Extended-Release Tablets

Expectorant & Nasal Decongestant

36 Extended-Release Tablets

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Keep the carton.
It contains important information.
See end panel for expiration date.

†All trademarks are property of their respective owners. MUCINEX is a registered trademark of RB HEALTH (US) LLC.

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512
Made in England R0519

N 3 51660 07136 8

½ GLUE - NO COATING

5188213

GUAIFENESIN AND PSEUDOEPHEDRINE HYDROCHLORIDE

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-071
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	600 mg
Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	xeuMnci;600
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51660-071-18	1 in 1 CARTON	12/10/2017	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-071-36	2 in 1 CARTON	12/10/2017	
2		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021585	11/15/2017	

Labeler - OHM LABORATORIES INC (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	MANUFACTURE(51660-071)

Revised: 6/2019 OHM LABORATORIES INC