

GUAIFENESIN AND PSEUDOEPHEDRINE HCL - guaifenesin and pseudoephedrine hcl tablet, extended release
Aurohealth LLC

Drug Facts

Active ingredients

(in each extended-release tablet)

Guaifenesin USP 600 mg

Pseudoephedrine HCl USP 60 mg

Purposes

Expectorant

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 extended-release 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 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

- store at 20 to 25°C (68 to 77°F)

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinised starch (maize).

Questions?

1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road

East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/60 mg (18 Tablet Carton Label)

AUROHEALTH

NDC 58602-833-12

***Compare to the active ingredients of Mucinex[®]D**

**Guaifenesin and
Pseudoephedrine Hydrochloride
Extended-Release Tablets
600 mg/60 mg**

**Guaifenesin 600 mg - Expectorant
Pseudoephedrine HCl 60 mg - Nasal Decongestant
RELIEVES NASAL & CHEST CONGESTION**

12 HOUR

- **Clears Nasal & Sinus Congestion**
- **Thins & Loosens Mucus**

18 Extended-Release Tablets



GUAIFENESIN AND PSEUDOEPHEDRINE HCL

guaifenesin and pseudoephedrine hcl tablet, extended release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58602-833 |
| 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 |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |

| | |
|--|--|
| MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK) | |
| MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y) | |
| POVIDONE K25 (UNII: K0KQV10C35) | |
| POVIDONE K90 (UNII: RDH86HJV5Z) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|----------|
| Color | WHITE (white to off-white) | Score | no score |
| Shape | OVAL (biconvex) | Size | 14mm |
| Flavor | | Imprint Code | 64;X |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58602-833-12 | 1 in 1 CARTON | 03/25/2020 | |
| 1 | | 18 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:58602-833-17 | 2 in 1 CARTON | 03/25/2020 | |
| 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 |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA213203 | 03/25/2020 | |

Labeler - Aurohealth LLC (078728447)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|--|
| APL HEALTHCARE LIMITED | | 650918514 | ANALYSIS(58602-833) , MANUFACTURE(58602-833) |

Revised: 9/2024

Aurohealth LLC