

**GUAIFENESIN- guaifenesin solution**  
**PAI Holdings, LLC dba PAI Pharma**

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**GUAIFENESIN**

*Expectorant*  
*SUGAR FREE / ALCOHOL FREE*

**DESCRIPTION**

Each 5 mL (1 teaspoonful) contains:  
Guaifenesin 100 mg

**Inactive Ingredients**

Acesulfame K, citric acid, FD&C Green No. 3, FD&C Red No. 40, flavoring, hydroxyethylcellulose, purified water, sodium benzoate and sodium citrate.

*Sodium Content: 4 mg/5 mL*

**USES**

Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

**WARNINGS**

**Ask a doctor before use if you have**

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Stop use and ask a doctor if**

- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- you are hypersensitive to any of the ingredients.

**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.

**Professional Note**

Guaifenesin has been shown to produce a color interference with certain clinical

laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

## DIRECTIONS

Follow dosage below or use as directed by a physician.

- do not take more than 6 doses in any 24-hour period.

| age                                   | dose                                                  |
|---------------------------------------|-------------------------------------------------------|
| adults and children 12 years and over | 10 to 20 mL<br>(2 to 4 teaspoonfuls)<br>every 4 hours |
| children 6 years to under 12 years    | 5 to 10 mL<br>(1 to 2 teaspoonfuls)<br>every 4 hours  |
| children 2 to under 6 years of age    | 2.5 to 5 mL<br>(½ to 1 teaspoonful)<br>every 4 hours  |
| children under 2 years of age         | consult a physician                                   |

Guaifenesin Oral Solution USP is a red, raspberry flavored solution supplied in the following oral dosage forms:

NDC 0121-0744-04: 4 fl oz (120 mL) bottle  
NDC 0121-0744-08: 8 fl oz (237 mL) bottle  
NDC 0121-0744-16: 16 fl oz (473 mL) bottle

NDC 0121-1744-05: 5 mL unit dose cup  
NDC 0121-1744-00: Case contains 100 unit dose cups of 5 mL (0121-1744-05) packaged in 10 trays of 10 unit dose cups each.

NDC 0121-1488-10: 10 mL unit dose cup  
NDC 0121-1488-00: Case contains 100 unit dose cups of 10 mL (0121-1488-10) packaged in 10 trays of 10 unit dose cups each.

NDC 0121-2232-15: 15 mL unit dose cup  
NDC 0121-2232-00: Case contains 100 unit dose cups of 15 mL (0121-2232-15) packaged in 10 trays of 10 unit dose cups each.

## STORAGE

Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F). [See USP] Protect from light.

## PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

**NDC 0121-0744-16**

**Quality**®

## Value

### Guaifenesin Oral Solution USP

100 mg/5 mL

#### EXPECTORANT

Compare to the active ingredient in

\*Robitussin®

**SUGAR FREE/ALCOHOL FREE  
LOOSENS AND RELIEVES  
CHEST CONGESTION**

16 fl oz (473 mL)

**Pharmaceutical  
Associates, Inc.**

Greenville, SC 29605

| <p><b>Drug Facts</b></p> <p><b>Active ingredient (in each 5 mL teaspoonful)</b> Purpose<br/>Guaifenesin 100 mg..... Expectorant</p> <p><b>Uses</b></p> <ul style="list-style-type: none"><li>■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive</li></ul> <p><b>Warnings</b></p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"><li>■ cough that occurs with too much phlegm (mucus)</li><li>■ cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema</li></ul> <p><b>Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.</b></p> <p><b>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p> | <p>NDC 0121-0744-16</p> <p><b>Quality Value®</b></p> <p><b>Guaifenesin<br/>Oral Solution USP</b></p> <p><b>100 mg/5 mL</b></p> <p><b>EXPECTORANT</b></p> <p>Compare to the active ingredient in *Robitussin®</p> <p><b>SUGAR FREE/ALCOHOL FREE<br/>LOOSENS AND RELIEVES<br/>CHEST CONGESTION</b></p> <p>16 fl oz (473 mL)</p> <p><b>pai Pharmaceutical Associates, Inc.</b><br/>Greenville, SC 29605</p> | <p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"><li>■ do not take more than 6 doses in any 24-hour period</li></ul> <table border="1"><thead><tr><th>age</th><th>dose</th></tr></thead><tbody><tr><td>adults and children 12 years and over</td><td>2-4 teaspoonfuls every 4 hours</td></tr><tr><td>children 6 years to under 12 years</td><td>1-2 teaspoonfuls every 4 hours</td></tr><tr><td>children 2 years to under 6 years</td><td>1/2-1 teaspoonful every 4 hours</td></tr><tr><td>under 2 years</td><td>ask a doctor</td></tr></tbody></table> <p><b>Other information</b></p> <ul style="list-style-type: none"><li>■ store at 20° -25° C (68° -77° F)</li><li>■ packaged with tamper evident seal around cap</li><li>■ sodium content 4 mg/5 mL</li></ul> <p><b>Inactive ingredients:</b> Acesulfame K, citric acid, FD&amp;C Green No. 3, FD&amp;C Red No. 40, flavoring, hydroxyethylcellulose, purified water, sodium benzoate and sodium citrate.</p> | age | dose | adults and children 12 years and over | 2-4 teaspoonfuls every 4 hours | children 6 years to under 12 years | 1-2 teaspoonfuls every 4 hours | children 2 years to under 6 years | 1/2-1 teaspoonful every 4 hours | under 2 years | ask a doctor |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|------|---------------------------------------|--------------------------------|------------------------------------|--------------------------------|-----------------------------------|---------------------------------|---------------|--------------|
| age                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | dose                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |     |      |                                       |                                |                                    |                                |                                   |                                 |               |              |
| adults and children 12 years and over                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 2-4 teaspoonfuls every 4 hours                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |     |      |                                       |                                |                                    |                                |                                   |                                 |               |              |
| children 6 years to under 12 years                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 1-2 teaspoonfuls every 4 hours                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |     |      |                                       |                                |                                    |                                |                                   |                                 |               |              |
| children 2 years to under 6 years                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 1/2-1 teaspoonful every 4 hours                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |     |      |                                       |                                |                                    |                                |                                   |                                 |               |              |
| under 2 years                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | ask a doctor                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |     |      |                                       |                                |                                    |                                |                                   |                                 |               |              |

\*Robitussin® is a registered trademark of Wyeth Consumer Healthcare.

## PRINCIPAL DISPLAY PANEL - 5 mL Cup Label

Delivers 5 mL

NDC 0121-1744-05

**G UAIFENESIN O RAL S OLUTION USP**

100 mg/5 mL

**Sugar Free/Alcohol Free**

**EXPECTORANT**

**Package Not Child-Resistant**

PHARMACEUTICAL ASSOCIATES, INC.  
GREENVILLE, SC 29605

**SEE INSERT**



**PRINCIPAL DISPLAY PANEL - 10 mL Cup Label**

**Delivers 10 mL**

**NDC 0121-1488-10**

**G UAIFENESIN O RAL S OLUTION USP**

**200 mg/10 mL**

**Sugar Free/Alcohol Free**

**EXPECTORANT**

**Package Not Child-Resistant**

PHARMACEUTICAL ASSOCIATES, INC.  
GREENVILLE, SC 29605

**SEE INSERT**



**PRINCIPAL DISPLAY PANEL - 15 mL Cup Label**

**Delivers 15 mL**

**NDC 0121-2232-15**

**G UAIFENESIN O RAL S OLUTION USP**

**300 mg/15 mL**

**Sugar Free/Alcohol Free**

**EXPECTORANT**

**Package Not Child-Resistant**

PHARMACEUTICAL ASSOCIATES, INC.  
GREENVILLE, SC 29605

**SEE INSERT**



## GUAIFENESIN

guaifenesin solution

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0121-0744 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name                                                       | Basis of Strength | Strength       |
|-----------------------------------------------------------------------|-------------------|----------------|
| <b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN       | 100 mg in 5 mL |

### Inactive Ingredients

| Ingredient Name                                | Strength |
|------------------------------------------------|----------|
| <b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9) |          |
| <b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S) |          |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)  |          |

**HYDROXYETHYL CELLULOSE, UNSPECIFIED** (UNII: T4V6TWG28D)

**WATER** (UNII: 059QF0KO0R)

**SODIUM BENZOATE** (UNII: OJ245FE5EU)

**SODIUM CITRATE, UNSPECIFIED FORM** (UNII: 1Q73Q2JULR)

**ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL)

### Product Characteristics

|                 |           |                     |  |
|-----------------|-----------|---------------------|--|
| <b>Color</b>    | red       | <b>Score</b>        |  |
| <b>Shape</b>    |           | <b>Size</b>         |  |
| <b>Flavor</b>   | RASPBERRY | <b>Imprint Code</b> |  |
| <b>Contains</b> |           |                     |  |

### Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:0121-0744-04 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/01/2002           |                    |
| 2 | NDC:0121-0744-08 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/01/2002           |                    |
| 3 | NDC:0121-0744-16 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/01/2002           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M012                                     | 09/01/2002           |                    |

## GUAIFENESIN

guaifenesin solution

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0121-1744 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name                                                       | Basis of Strength | Strength       |
|-----------------------------------------------------------------------|-------------------|----------------|
| <b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN       | 100 mg in 5 mL |

### Inactive Ingredients

| Ingredient Name                                | Strength |
|------------------------------------------------|----------|
| <b>ACESULFAME POTASSIUM</b> (UNII: 230V73Q5G9) |          |
| <b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S) |          |

|                                                               |  |
|---------------------------------------------------------------|--|
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                 |  |
| <b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D) |  |
| <b>WATER</b> (UNII: 059QF0KO0R)                               |  |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)                     |  |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)    |  |
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)               |  |

### Product Characteristics

|                 |           |                     |  |
|-----------------|-----------|---------------------|--|
| <b>Color</b>    | red       | <b>Score</b>        |  |
| <b>Shape</b>    |           | <b>Size</b>         |  |
| <b>Flavor</b>   | RASPBERRY | <b>Imprint Code</b> |  |
| <b>Contains</b> |           |                     |  |

### Packaging

| # | Item Code        | Package Description                                         | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:0121-1744-00 | 10 in 1 CASE                                                | 09/01/2002           |                    |
| 1 |                  | 10 in 1 TRAY                                                |                      |                    |
| 1 | NDC:0121-1744-05 | 5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M012                                     | 09/01/2002           |                    |

## GUAIFENESIN

guaifenesin solution

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0121-1488 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name                                                       | Basis of Strength | Strength        |
|-----------------------------------------------------------------------|-------------------|-----------------|
| <b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN       | 200 mg in 10 mL |

### Inactive Ingredients

| Ingredient Name                                 | Strength |
|-------------------------------------------------|----------|
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) |          |
| <b>ACESULFAME POTASSIUM</b> (UNII: 230V73Q5G9)  |          |



|                                                               |  |
|---------------------------------------------------------------|--|
| <b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)                |  |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                 |  |
| <b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D) |  |
| <b>WATER</b> (UNII: 059QF0KO0R)                               |  |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)                     |  |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)    |  |

| Product Characteristics |           |                     |  |
|-------------------------|-----------|---------------------|--|
| <b>Color</b>            | red       | <b>Score</b>        |  |
| <b>Shape</b>            |           | <b>Size</b>         |  |
| <b>Flavor</b>           | RASPBERRY | <b>Imprint Code</b> |  |
| <b>Contains</b>         |           |                     |  |

| Packaging |                  |                                                              |                      |                    |
|-----------|------------------|--------------------------------------------------------------|----------------------|--------------------|
| #         | Item Code        | Package Description                                          | Marketing Start Date | Marketing End Date |
| 1         | NDC:0121-1488-00 | 10 in 1 CASE                                                 | 09/01/2002           |                    |
| 1         |                  | 10 in 1 TRAY                                                 |                      |                    |
| 1         | NDC:0121-1488-10 | 10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product |                      |                    |

| Marketing Information |                                          |                      |                    |
|-----------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug    | M012                                     | 09/01/2002           |                    |

## GUAIFENESIN

guaifenesin solution

| Product Information            |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0121-2232 |
| <b>Route of Administration</b> | ORAL           |                           |               |

| Active Ingredient/Active Moiety                                       |                   |                 |
|-----------------------------------------------------------------------|-------------------|-----------------|
| Ingredient Name                                                       | Basis of Strength | Strength        |
| <b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN       | 300 mg in 15 mL |

| Inactive Ingredients                            |          |
|-------------------------------------------------|----------|
| Ingredient Name                                 | Strength |
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) |          |

|                                                               |  |
|---------------------------------------------------------------|--|
| <b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)                |  |
| <b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)                |  |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                 |  |
| <b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D) |  |
| <b>WATER</b> (UNII: 059QF0KO0R)                               |  |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)                     |  |
| <b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)    |  |

### Product Characteristics

|                 |           |                     |  |
|-----------------|-----------|---------------------|--|
| <b>Color</b>    | red       | <b>Score</b>        |  |
| <b>Shape</b>    |           | <b>Size</b>         |  |
| <b>Flavor</b>   | RASPBERRY | <b>Imprint Code</b> |  |
| <b>Contains</b> |           |                     |  |

### Packaging

| # | Item Code        | Package Description                                          | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:0121-2232-00 | 10 in 1 CASE                                                 | 09/01/2002           |                    |
| 1 |                  | 10 in 1 TRAY                                                 |                      |                    |
| 1 | NDC:0121-2232-15 | 15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M012                                     | 09/01/2002           |                    |

### Labeler - PAI Holdings, LLC dba PAI Pharma (044940096)

### Establishment

| Name                                                                     | Address | ID/FEI    | Business Operations                                     |
|--------------------------------------------------------------------------|---------|-----------|---------------------------------------------------------|
| PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma |         | 097630693 | manufacture(0121-0744, 0121-1744, 0121-1488, 0121-2232) |

Revised: 6/2022

PAI Holdings, LLC dba PAI Pharma