Dear Healthcare Professional,

At MPR we strive to bring you important drug information in a concise and timely manner. In keeping with this goal, we are pleased to bring you this CLINICAL ALERT announcing results of a clinical study evaluating the benefits of adding MUCINEX® D (600 mg guaifenesin and 60 mg pseudoephedrine HCl extended-release bi-layer tablets) for symptom relief to an antibiotic for patients with an acute respiratory infection (ARI).

MUCINEX D, from Reckitt Benckiser Inc., is the first and only OTC medicine* to be evaluated in a multicenter, randomized, parallel-group, double-blind, placebo-controlled study; the study’s objective was to examine efficacy and safety of MUCINEX D in providing relief of respiratory symptoms when used as an adjunct to an antibiotic for patients with an ARI. Patients were prescribed an antibiotic regimen, plus 2 MUCINEX D tablets or matching placebo, twice daily (morning and evening) for 7 days.†

Study results demonstrated the addition of MUCINEX D to an antibiotic regimen significantly shortened time to relief and improved total respiratory symptoms.‡ The total symptom score significantly improved by Day 3 of the study for patients taking an antibiotic with MUCINEX D compared to patients taking an antibiotic with placebo ($P=0.026$). In as little as 2 days, significantly more patients taking an antibiotic with MUCINEX D felt “the medication was helping during the day” compared to patients taking an antibiotic with placebo ($P=0.002$).

Overall, patients preferred the effectiveness of an antibiotic with MUCINEX D for respiratory symptom relief compared to an antibiotic with placebo ($P=0.021$). In addition, 82.2% of investigating physicians in the antibiotic + MUCINEX D group would recommend this combination to their patients for relief of symptoms associated with an ARI.$^*$

*Based on a search (several databases, including PubMed, as of August 24, 2009) of clinical trials conducted over the past 10 years in which an OTC medication containing guaifenesin and pseudoephedrine HCl was used as an adjunct to an antibiotic.

†The primary endpoint was a composite endpoint including 10 symptoms of ARI: 4 symptoms (chest congestion, thickened sputum or phlegm, nasal congestion, facial pain/pressure/tenderness) are approved uses for MUCINEX D while the remaining 6 symptoms (runny nose, sinus headache, sore throat, postnasal drip, cough, breathlessness) are not.$^*$ Each symptom was also evaluated separately, and while the mean individual symptom scores tended to show more improvement with MUCINEX D than with placebo, only nasal congestion ($P=0.012$) and sinus headache ($P=0.022$) were statistically significant versus placebo.

(continued on back)
‡MUCINEX D is approved to: help loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive; temporarily relieve nasal congestion due to common cold, hay fever, upper respiratory allergies; temporarily restore freer breathing through the nose; promote nasal and/or sinus drainage; temporarily relieve sinus congestion and pressure.2

The combined regimen was well-tolerated; the most common adverse events were: insomnia, nausea and headache.

We are interested in learning more about your recommendation habits for patients prescribed an antibiotic for an acute respiratory infection. Please review, complete, and return the attached survey. To show our appreciation, you will receive a $5 check in the mail upon receipt of your completed survey.

Please visit www.mucinex.com/professional and see the MUCINEX D Product Label for more information.

More information on MUCINEX D is also available in the current edition of MPR.

Sincerely,

Grace L. McBride
Editorial Director
MPR Custom Programs

REFERENCES
2. MUCINEX D product labeling.
The first and only published placebo-controlled study to examine the benefits of an OTC medicine* (MUCINEX D) for symptom relief as an adjunct to an antibiotic in the treatment of an acute respiratory infection (ARI)

- Evaluated in a multicenter, randomized, parallel-group, double-blind, placebo-controlled study in 601 adult patients as an adjunct to an antibiotic for relief of symptoms associated with an ARI\(^1\)

Proven in a clinical study: MUCINEX D helps patients feel better faster when combined with an antibiotic for patients with an ARI\(^1\)

Study results show the addition of MUCINEX D to an antibiotic regimen significantly shortens time to relief and improves total respiratory symptoms (\(P=0.026\))\(^1\)

- Starting on Day 3 patients taking an antibiotic + MUCINEX D showed significant improvement in total symptom score vs patients taking an antibiotic + placebo (\(P=0.026\))\(^1\) (Figure 1)

Company: Reckitt Benckiser Inc.  
OTC

Pharmacological class: Expectorant + nasal decongestant

Active ingredients: Guaifenesin 600 mg + pseudoephedrine HCl 60 mg: extended-release bi-layer tablets

Indications: Chest and nasal congestion.

Sinus pressure.

Adults: Swallow whole. 2 tablets every 12 hours. Max: 4 tablets/day.

Children: <12 years: do not use.

Contraindications: During or within 14 days of MAOIs.


Interactions: Hypertensive crisis with MAOIs (see Contraindications).

Adverse reactions: GI upset, drowsiness, headache, rash, dizziness, nervousness, insomnia.

How supplied: MUCINEX D–18, 36; Maximum Strength MUCINEX D–24

Figure 1

MEAN TOTAL SYMPTOM SCORE

<table>
<thead>
<tr>
<th>Day</th>
<th>Symptom score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10.6</td>
</tr>
<tr>
<td>3</td>
<td>11.6</td>
</tr>
</tbody>
</table>

Source: Data on file.\(^2\)
• Median time to attain significant relief\(^8\) was significantly shorter in patients taking an antibiotic + MUCINEX D vs an antibiotic + placebo for nasal congestion (4.75 vs 5.75 days; [log rank test, \(P=0.015\); Wilcoxon test, \(P=0.015\)])\(^1\)

☑ Significantly more patients taking an antibiotic + MUCINEX D felt “the medication was helping during the day” as early as Day 2 of the study \((P=0.002)\)\(^1\) (Figure 2)

☑ Patients preferred the effectiveness of an antibiotic + MUCINEX D for respiratory symptom relief vs placebo with an antibiotic \((P=0.021)\)\(^1\)

☑ 82.2% of investigating physicians (a rate of 5 to 1) in the antibiotic + MUCINEX D group would recommend MUCINEX D as an adjunct to antibiotics for relief of symptoms associated with an ARI in the future\(^1\)

☑ The combined regimen was well-tolerated; the most common adverse events were: insomnia, nausea and headache.

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§Significant relief is defined as a 2-grade reduction from baseline score sustained throughout the study.\(^1\)

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REFERENCES
3. MUCINEX D product labeling.