## Brompheniramine Maleate, Pseudoephedrine Hydrochloride, and Dextromethorphan Hydrobromide IMPORTANT SAFETY INFORMATION

- Brompheniramine maleate, pseudoephedrine hydrochloride, and dextromethorphan hydrobromide, 2mg/30mg/10mg, is indicated for relief of cough and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold
- Brompheniramine maleate, pseudoephedrine hydrochloride, and dextromethorphan hydrobromide, 2mg/30mg/10mg, is contraindicated in patients with hypersensitivity to any of the ingredients. Brompheniramine maleate, pseudoephedrine hydrochloride, and dextromethorphan hydrobromide, 2mg/30mg/10mg, should not be used in newborns, in premature infants, in nursing mothers, or in patients with severe hypertension or severe coronary artery disease. Brompheniramine maleate, pseudoephedrine hydrochloride, and dextromethorphan hydrobromide, 2mg/30mg/10mg, should not be used in patients receiving monoamine oxidase (MAO) inhibitors. Antihistamines should not be used to treat lower respiratory tract conditions including asthma
- Especially in infants and small children, antihistamines in overdosage may cause hallucinations, convulsions, and death. Antihistamines may diminish mental alertness. In the young child, they may produce excitation
- The most frequent adverse reactions to Brompheniramine maleate, pseudoephedrine hydrochloride, and dextromethorphan hydrobromide, 2mg/30mg/10mg, bare sedation; dryness of mouth, nose, and throat; thickening of bronchial secretions; and dizziness

To report SUSPECTED ADVERSE REACTIONS, contact Acella Pharmaceuticals at 1-800-541-4802 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



