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The Panel suggests the deletion from the package insert of the following statements, which pertain to the individual ingredients of the combination and not necessarily to the combination; these statements should be so phrased that they do not imply that the same individual action occurs with the combination, unless such action can be demonstrated:

Tuazole (methaqualone) has been shown to be a potent and effective calming agent with a low order of toxicity.

Tuazole (methaqualone) has several qualities of both short-acting barbiturates and mephenesin.

As a calming agent, Tuazole (methaqualone) is desirable and lends itself ideally to prolongation through ionic release from its resin complex. These properties make Tuazole ideal for decreasing the hyperactivity associated with amphetamine therapy in some patients.

Approved by .

Chairman