

- 5 -

Spontaneous vomiting and increased secretions are common and may lead to aspiration pneumonia or respiratory obstruction. Large overdoses have been accompanied by cutaneous edema, pulmonary edema, hepatic damage, renal insufficiency, and bleeding. Overdoses of methaqualone appear to be less often associated with cardiac or respiratory depression than are overdoses of the oral barbiturates, but shock and respiratory arrest may occasionally occur. Coma has occurred with acute overdoses of methaqualone averaging 2.4 gm. Death has occurred following ingestion of 8 gms. In other cases, patients have survived the ingestion of up to 22 grams of methaqualone. Most fatal cases have followed ingestion of overdoses accompanied by alcohol.

Recommended management includes prompt evacuation of gastric contents, maintenance of adequate ventilation, support of blood pressure if necessary, and the usual supportive measures for the unconscious patient.

Dialysis may be helpful. Analeptics are contraindicated.

Use of succinylcholine accompanied by assisted respiration has been proposed for prolonged convulsions.

HOW SUPPLIED: (to be supplied by firm).

The change should be made as soon as possible, and in any case, within 30 days of receipt of this letter.

Please let us know within 15 days of receipt of this letter your proposal in regard to the above recommendation.

Sincerely yours,

Barrett Scoville

Barrett Scoville, M.D.
Deputy Director
Division of Neuropharmacological
Drug Products
Office of Scientific Evaluation
Bureau of Drugs