1969 numerous reports of fatalities and serious reactions in children who accidentally ingested Lomotil tablets appeared.4-9 Even with the accidental overdosage of relatively small amounts (six tablets for a 2-year-old child5), respiratory failure and cardiac arrest have occurred. A recent report to the FDA described prolonged respiratory depression in a 22-month-old infant who ingested five tablets of Lomotil. The serious adverse effects are compounded because both constituents of the combination, diphenoxylate hydrochloride and atropine sulfate, contribute to the poisoning.

Following these reports, FDA reviewed the use of Lomotil in the pediatric age group.

DISCUSSION

Each Lomotil tablet or 5 ml of liquid contains 2.5 mg diphenoxylate hydrochloride and 0.025 mg atropine sulfate. The National Formulary designates diphenoxylate hydrochloride as an "antidiarrheal (narcotic)."4-13 It is chemically related to meperidine hydrochloride (Demerol).4,11-13 Fraser and Isbell call diphenoxylate hydrochloride a "congener of meperidine."

A comparison of the two chemical structures is shown:

Warning: The Use of Lomotil in Children

Recently a father wrote the Food and Drug Administration (FDA) concerning the death of his child from accidental ingestion of Lomotil tablets. He bore the blame for leaving the "pills" where the child had been able to reach them. He had thought they were a harmless medication for diarrhea.

On December 3, 1969, the New York Times carried a column entitled "Children Periled by an Adult Drug," commenting on a paper delivered at the American Medical Association's clinical session. The article stated that "children who accidentally swallow a few tablets of a commonly prescribed antidiarrheal drug can get severe breathing difficulty, lose consciousness and sometimes die. . . ." "This illustrates a general problem—a small amount of medication that is safe for adults can be harmful to children." The article stated further: "there is no reason for the FDA to take it off the market but doctors should be aware that children are sensitive to it."

Lomotil, as a remedy for diarrhea, was approved by FDA in tablet form in 1960 and in liquid form in 1961. Until 1969 there were only sporadic reports in the literature of accidental ingestion by children.2,3 However, in 1969 numerous reports of fatalities and serious reactions in children who accidentally ingested Lomotil tablets appeared.4-9 Even with the accidental overdosage of relatively small amounts (six tablets for a 2-year-old child5), respiratory failure and cardiac arrest have occurred. A recent report to the FDA described prolonged respiratory depression in a 22-month-old infant who ingested five tablets of Lomotil. The serious adverse effects are compounded because both constituents of the combination, diphenoxylate hydrochloride and atropine sulfate, contribute to the poisoning.

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