

Favorable acute toxicity profile of morclofone in children

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Objectives

Morclofone, a centrally acting non-narcotic antitussive, is used in the treatment of non-productive cough in some European countries since the 1980s, mainly in pediatric patients in form of a sucrose containing syrup. The usual therapeutic single dose is 50 mg morclofone for children < 3years, and 150mg for older children. Morclofone seems to have a favorable side effect profile (ref.), but modern approval studies are lacking. The aim of this study was to determine the acute toxicity profile of morclofone in overdose, since available information is limited.

Methods

A retrospective review of acute morclofone mono-intoxications in children (<16years), that had been reported to our poisons centre between January 1997 and June 2016 with sufficient evidence of exposure and high causality. The severity of observed symptoms was graded according to the Poisoning Severity Score.

Results

- 29 patients, 10 (34.5%) females and 19 (65.5%) males with a mean age of 3 years (1.6-6 years), were included.
- No effects were reported in 8 cases, and minor symptoms in 21 cases. There were no moderate or severe cases, and no fatalities.
- In 21 cases the ingested dose was known, and this ranged from 31-171mg/kg morclofone (mean 64), corresponding to a 4- to 36-fold of the therapeutic single dose (mean: 9-fold). (Tab.1)
- Signs and symptoms predominantly involved the gastrointestinal and the central nervous system. (Tab. 2) All symptoms were of short duration and resolved spontaneously.
- In 11 of the 29 cases the latency between the ingestion and the onset of symptoms was known and was reported to be 30 to 120 min. (mean 60), which is in accordance to the T_{max}. of 60-120 min. of morclofone.
- Gastrointestinal decontamination consisting of a single dose of activated charcoal was performed in 9 patients; 2 of them remained without symptoms, and 7 developed mild symptoms.

Conclusions

Morclofone seems to have a favorable acute toxicity profile and significant overdoses up to 171mg/kg were tolerated by children with only mild effects, which were predominantly of gastrointestinal and neurological nature, consistent with the described adverse effects of this drug. Therefore, observation at home without gastrointestinal decontamination seems reasonable after ingesting less than 171mg/kg.

Morclofone

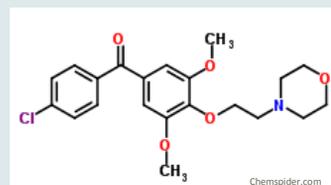


Table 1: Clinical course and ingested morclofone dose (n=21)

Clinical course (number of patients)	Ingested morclofone dose range; mean (mg/kg)	Several fold of the single therapeutic dose range; mean
No symptoms (n= 6)	31 - 82; 59	6 - 30; 14
Minor (n= 15)	33 - 171; 67	4 - 36; 7

Table 2: Symptoms and signs in the 21 symptomatic patients

	Symptom/Sign	Frequency
Gastrointestinal system	Vomiting	15
	Nausea	4
	Abdominal pain	4
Central nervous system	Drowsiness	4
	Somnolence	4
	Ataxia	1
Cardiovascular system	Tachycardia	1



Bottle with 180 ml syrup: 1800 mg morclofone