



Dr. Troutman

Introductory remarks

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When alphaprodine* (Nisentil®) was recalled from the market by Roche Laboratories in September of 1980 because of reports of several adverse drug reactions which were apparently associated with its incorrect use (outside the recommendations in the package insert), many pedodontists became alarmed. Here was a drug that many of us thought was a very effective and safe drug for sedating young children, and it was being taken off the market because of misuse by uninformed colleagues.

The *Product Return Notice* stated that the availability of alternative medications was a primary reason for the decision. The notice also stated that Roche Laboratories considered a communications program concerning the drug's use. They decided against this approach because the effectiveness of such a program could not be guaranteed.

It quickly became clear that if we were ever going to be using alphaprodine again, two things would have to be accomplished:

1. Data would have to be collected to substantiate the claim that alphaprodine is a safe and effective drug for use in pedodontics.
2. An educational campaign would need to be conducted to inform dentists how to use the drug properly and safely.

Under the direction of Dr. Diane T. Chen, Assistant Director of Professional Services for Roche Laboratories, retrospective data was collected from numerous members of the American Academy of Pedodontics and evaluated in an effort to establish an effective and safe dose for alphaprodine in children undergoing dental treatment.

The results of this study were submitted to the Federal Drug Administration for their review,

*Alphaprodine hydrochloride (dl-1, 3-dimethyl-4-phenyl-piperidinol propionate hydrochloride) — for simplicity, *alphaprodine* will be used in this proceedings.

along with recommendations for a new package insert to include doses for pediatric dental patients.

In 1981 the American Academy of Pedodontics sponsored a panel on alphaprodine at their annual scientific meeting. At that time it became quite clear that there was a great deal of interest in this drug among our members.

The final step is this symposium and the publication of its proceedings — not only to the members of our Academy, but for the entire dental profession.

Through the efforts of Dr. Chen, other Roche personnel, and several members of the American Academy of Pedodontics; and, utilizing funding provided by Roche Laboratories, this symposium and the publication of these proceedings has been made possible.

The intent of this symposium is to communicate to dentists who sedate children when providing dental treatment, a safe and effective approach to the use of sedation in general and alphaprodine in particular, by: (1) presenting current research data in the use of alphaprodine, (2) reviewing the state of the art of sedating children for dental treatment, (3) presenting successful clinical techniques for utilizing alphaprodine in a pediatric dental practice, and (4) utilizing the experience and expertise of the participants in this symposium to establish safe and effective guidelines for the use of alphaprodine in pedodontics.

Obviously, we who are a part of this symposium do not have all the answers. However, the papers and the discussion that are assembled here as a supplement to *Pediatric Dentistry* should serve as a valuable source of current knowledge for every dentist who utilizes sedative drugs (particularly alphaprodine) in their treatment of children.

I wish to express my gratitude to Roche Laboratories for making this symposium possible,

to the American Academy of Pedodontics for both sponsoring it and for publishing the proceedings as a supplement to their journal, and to the essayers who have contributed their time and expertise in making these proceedings a valuable educational resource for our specialty

and the dental profession as a whole.

Finally a special thanks goes to Dr. Diane T. Chen who has spent a great deal of time over the past year in an effort to make a safe and valuable tool available to pedodontists.

The following lists may aid the reader in those instances where a trademark or chemical name may be unfamiliar.

Trademark	Chemical Name	Chemical Name	Trademark
Atarax®	hydroxyzine hydrochloride	alphaprodine hydrochloride	Nisentil®
Benadryl®	diphenhydramine hydrochloride	chloral hydrate	Noctec®
Demerol®	meperidine (pethidine) hydrochloride	chlorpromazine hydrochloride	Thorazine®
Dramamine®	dimenhydrinate hydrochloride	diazepam	Valium®
Ketaject®	ketamine hydrochloride	dimenhydrinate hydrochloride	Dramamine®
Ketalar®	ketamine hydrochloride	diphenhydramine hydrochloride	Benadryl®
Lorfan®	levorphan tartrate	fentanyl citrate	Sublimaze®
Nalline®	nalorphine	hydroxyzine hydrochloride	Atarax®, Vistaril®
Narcan®	naloxone hydrochloride	ketamine hydrochloride	Ketaject®, Ketalar®
Nisentil®	alphaprodine hydrochloride	levorphan tartrate	Lorfan®
Noctec®	chloral hydrate	lidocaine (preparations)	Xylocaine®
Phenergan®	promethazine hydrochloride	meperidine hydrochloride	Demerol®
Seconal®	secobarbital	nalorphine	Nalline®
Sparine®	promazine hydrochloride	naloxone hydrochloride	Narcan®
Sublimaze®	fentanyl citrate	promazine hydrochloride	Sparine®
Thorazine®	chlorpromazine hydrochloride	promethazine hydrochloride	Phenergan®
Valium®	diazepam	secobarbital	Seconal®
Vistaril®	hydroxyzine hydrochloride		
Xylocaine®	lidocaine preparations		