

the nasal cavities, of which 278 received GOPRELTO (4% solution), 275 received cocaine hydrochloride solution 8%, and 95 received placebo. Safety was evaluated for up to 7 days after dosing.

The most commonly reported adverse reactions (>1 patient) to occur in the Phase 3 study with GOPRELTO (4% solution) were headache and epistaxis. Two adverse reactions of headache were severe (Table 1).

No premature discontinuations due to an adverse event, serious adverse events, or deaths were reported in the Phase 3 clinical study.

Table 1: Common Adverse Reactions with GOPRELTO in >1 Patient

System Organ Class / Preferred Term	GOPRELTO 4% (N=278)	Cocaine Hydrochloride Solution 8% (N=275)	Placebo (N=95)
Nervous System Disorders			
Headache	7 (3%)	4 (2%)	1 (1%)
Respiratory, Thoracic, and Mediastinal Disorders			
Epistaxis	3 (1%)	2 (1%)	0
Psychiatric Disorders			
Anxiety	0	2 (1%)	0

7 DRUG INTERACTIONS

7.1 Disulfiram

Published literature reported that disulfiram treatment increased plasma cocaine exposure, including both AUC and C_{max}, by several fold after acute intranasal cocaine administration. Other literature reported that co-administration of disulfiram increased AUC of plasma cocaine by several fold after intravenous cocaine administration [see *Clinical Pharmacology* (12.3)].

Avoid using GOPRELTO in patients taking disulfiram. Consider using other local anesthetic agents.

7.2 Epinephrine, Phenylephrine

There are reports in the published literature of myocardial ischemia, myocardial infarction, and ventricular arrhythmias after concomitant administration of topical intranasal cocaine with epinephrine and phenylephrine during nasal and sinus surgery.

Avoid use of additional vasoconstrictor agents such as epinephrine and phenylephrine with GOPRELTO during nasal and sinus surgery. If concomitant use is unavoidable, prolonged vital sign and ECG monitoring may be required [see *Warnings and Precautions* (5.3)].