RAPID AND SUSTAINED IMPROVEMENT IN MIGRAINE SYMPTOMS WITH A NEW POWDERED FORMULATION OF DICLOFENAC POTASSIUM FOR ORAL SOLUTION: RESULTS FROM 2 RANDOMIZED, CONTROLLED CLINICAL TRIALS

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BACKGROUND: CAMBIA™ (diclofenac potassium for oral solution) is a unique, readily soluble, powdered formulation of diclofenac potassium.
OBJECTIVE: To determine the efficacy, time to onset of action, sustained effect, and safety of CAMBIA following treatment of acute migraine attacks.
METHODS: A randomized, controlled, crossover European trial evaluated CAMBIA 50-mg sachets, diclofenac potassium tablets, and placebo in 317 adults with migraine (888 attacks). A second randomized, controlled, parallel-group trial in the US evaluated CAMBIA and placebo in 690 adults with migraine. In both trials, patients self treated a moderate-to-severe migraine attack with 1 dose of study medication or placebo and evaluated pain up to 24-hours post dose.
RESULTS: CAMBIA exhibited rapid onset of action (15 minutes vs 60 minutes for diclofenac tablets in the European trial, 30 minutes in the US trial vs placebo). Clinically important and statistically significant superiority over placebo was reported in both trials with CAMBIA for freedom from headache pain, nausea, photophobia, phonophobia, and headache response at 2-hours post dose. Sustained headache response and pain freedom were superior to placebo at 24 hours. CAMBIA was significantly superior to diclofenac tablets for pain freedom at 2 hours and sustained pain freedom for 24 hours in the European trial. The incidence of adverse events was comparable to placebo and there were no serious adverse events.
CONCLUSIONS: These results demonstrate that CAMBIA is a safe and effective treatment for a migraine attack. Patients will benefit from the fast onset of action, overall effectiveness, and sustained effect provided by CAMBIA in the acute treatment of migraine.

European Trial	**CAMBIA Sachet** (n=291)	**Placebo** (n=299)	**Diclofenac Potassium Tablet** (n=298)
2-hour pain free	24.7%	11.7%	18.5%
2-hour symptom free	41.9%	29.6%	40.5%
2-hour headache response	46%	24.1%	41.6%
2-hour improved working ability	50%	26.5%	42.7%
2-hour bed rest	7.6%	20.8%	15.2%
2-hour average VAS reduction	16.6 mm (n=276)	7 mm (n=289)	11.5 mm (n=286)
8-hour rescue medication	35.1%	50.2%	36.2%
2- to 24-hour pain free	22.3%	9.4%	15.1%
2- to 24-hour headache response	36.8%	18.4%	30.9%
Recurrence	15.5%	21.1%	21.8%

US Trial	**CAMBIA Sachet** (n=343)	**Placebo** (n=347)
2-hour pain free	25.1%	10.1%*
2-hour nausea free	64.7%	52.7%†
2-hour photophobia free	40.5%	27.4%*
2-hour phonophobia free	44.3%	27.4%*
2-hour headache response	64.7%	41.6%
2-hour restoration of function	33.2%	16.1%
30-minute pain intensity difference	0.4	0.3‡
2- to 24-hour pain free	19%	7.2%*
2- to 24-hour headache response	54.5%	36.9%
2- to 24-hour restoration of function	54.5%	36.9%
Recurrence	24%	29%