

GELSTAT MIGRAINE® FOR ACUTE TREATMENT OF MIGRAINE PAIN AND ASSOCIATED SYMPTOMS

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BACKGROUND

Migraine headaches affect up to 27 million Americans, less than half have been diagnosed by clinicians. Of those diagnosed with migraine more than 50% rely on over-the-counter medications (OTCs) to treat their headaches. Although non-prescription treatments are used due to availability, cost and perceived lack of side effects, they often fail to provide adequate relief.

GelStat Migraine® is a combination of natural products with active ingredients fever few and ginger. Both are considered safe and have been widely used for centuries. Fever few has been used as a migraine preventive and more recently for acute therapy. This treatment could provide substantial benefits to those sufferers preferring OTCs and provide a cost-effective alternative to prescription medications.

PRIMARY OBJECTIVE

To assess the efficacy of the non-prescription, sublingually administered, preparation of feverfew and ginger, "GelStat Migraine", in providing acute relief from migraine headache pain and associated symptoms.

SECONDARY OBJECTIVES

Evaluate persistent or recurrent headache 2-24 hours following treatment

Assess adverse events

Evaluate patient satisfaction with therapy

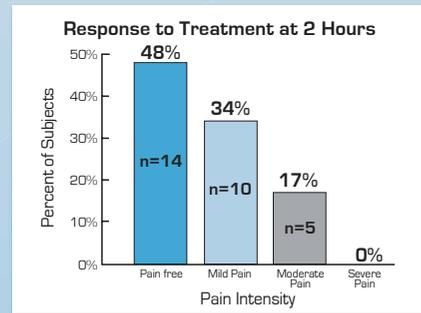
Evaluate patient preference for migraine treatment

METHOD OF STUDY

The study was conducted at a single headache specialty clinic enrolling 30 subjects with IHS diagnostic criteria (1988) for migraine without aura (IHS 1.1) or migraine with aura (IHS 1.2). Eligible subjects treated 1 migraine attack during the mild pain phase with GelStat Migraine. One treatment consisted of two 2 ml GelStat Migraine doses administered sublingually 5 minutes apart. A second treatment could be taken if needed for persistent or recurrent pain between 1 and 24 hours. Subjects recorded response to treatment in diaries.

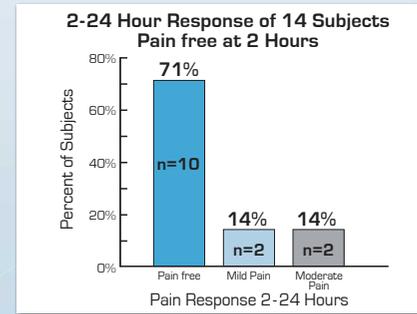
RESULTS

- 29 of 30 subjects completed the study.
- 48% (14/29) were pain free 2 hours after treatment of migraine during mild pain.
- 83% (24/29) were either pain free or had only mild pain 2 hours after treatment.

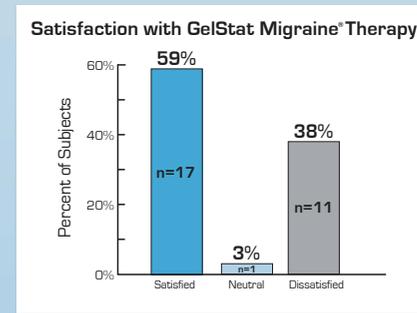


- Migraine associated symptoms were absent 2 hours after treatment in 53% of those initially reporting such symptoms (9/17).

- 34% of enrolled subjects, 71% (10/14) of responders, had a sustained pain-free response from 2-24 hours.



- Satisfaction with GelStat Migraine treatment was reported by 59% (17/29).



*Of the 14 responders at 2 hours, 12 were satisfied with GelStat Migraine therapy compared to pre-study therapy. 8 of the 14 subjects were using triptans alone or in combination with other therapies.

- 41% (12/29) preferred GelStat Migraine or felt it was equal to their pre-study medication.
- 4 subjects reported side effect
 - 3 disliked taste
 - 1 had transient burning under the tongue

SUMMARY

In this small open-label study, GelStat Migraine dosed during the mild pain phase of migraine

- Achieved pain-free results - 48% of subjects within 2 hours
- Relieved associated symptoms of migraine - 53% of subjects within 2 hours
- Sustained pain-free efficacy - 34% of subjects
- Side effects were infrequent and minor - 13% of subjects

CONCLUSIONS

Many patients with diagnosed and undiagnosed migraine rely on non-prescription treatment for their headaches. GelStat Migraine was effective in relieving acute migraine and preventing migraine progression when administered during mild migraine. GelStat Migraine may represent a new non-analgesic option for patients when used early. This study is limited by its small number of patients and open-label protocol. Further investigation of GelStat Migraine in the treatment of migraine is warranted.