Marshall-Blum, LLC
268 Hancock Street
Bangor, ME 04401
207 990 4963
207 990 1769 fax
info@marshallblum.com

Marshall-Blum, LLC

Clinical Outcome Specialists

James M. Blum, Ph.D.,CEO

BEST PAIN RELIEF
for INFLAMMATION AND PAIN

Best Pain Relief
Westboro, MA

January 4, 2002

www.marshallblum.com

Table of Contents

Executive Summary

Randomized, Placebo-Controlled Clinical Trial to Test the Efficacy and Short-Term Safety of Menastil, an Oil-Based Product Designed for External Use to Relieve Symptoms Associated with Menstrual Cramping

Product: Best Pain Relief Products Menastil
Client: Atlantic Management Resources Ltd.
Roger Salmonson, President

(508) 366-6311
(508) 366-1121 (fax)

Prepared By:
James M. Blum, Ph.D.
Ronald I. Blum, M.D. (not related)
Marshall-Blum, LLC
304 Hancock, Suite 3D
Bangor, Maine 04401
(207) 990-4963
(207) 990-1769 (fax)
info@marshallblum.com

January 11, 2002

Clinical Site:

Bangor, Maine:
Marshall-Blum: Clinical Outcomes Specialists (parent company)
Herbal Research Clinic
Independent Medical Research Center
James M. Blum, PhD, Study Coordinator, Epidemiologist and Biostatistician
Medical Director: Ronald I. Blum, MD
Medical Advisor: Felix Hernandez, MD

Protocol:

Design:

- Prospective, randomized, double blind placebo-based cross-over clinical trial
- This trial had IRB approval (IRB Study #: 001110-001: Fox Commercial IRB, Candice Woods, Exec. Director, Springfield, IL)
- Randomization determined who started on placebo and who started with the active product
- There was no washout period since this product is externally applied and is not believed to carry over it's effects for more than a few hours
- Menastil contains calendula oil in a homeopathic concentration
- The product and placebo were externally applied to the lower abdominal region, extending below the hip joint
- The material was applied many times during the day or night using the applicator provided with the product; the essential oils carry virtually no risk to the subject
- Each subject was required to do a screening test for one month (one cycle) before randomization
- All subject contact was with a study coordinator or research nurse who was blinded to the randomization scheme
- Subjects were recruited from the general population of Bangor, Maine; the major exclusion criteria were women with a history of severe gynecological pathology; specifically, those with a diagnosis of endometriosis

Product Usage:

Apply liberally to the lower abdominal region as needed.

Placebo Product:

The placebo was a similar oil to the actual product except that it contained no calendula oil. A small amount of an aromatic oil was substituted for the strong odor of calendula to mimic the product. The base of both products was identical.

Inclusion Criteria:

- Women with moderate-to-severe menstrual symptoms, including but not limited to cramping, pain, discomfort, or difficulty sleeping, who express an interest in taking the product for reasons of reducing menstrual cycle symptoms
- Women with regular menstrual cycles
- Age range: 14-40 Note: Subjects below 18 are required by law to have consent of a parent or guardian.
- Subjects who pass a compliance-screening test
- Subjects able to tolerate the active product and placebo
- Subjects who sign a consent form

Exclusion Criteria:

- Patients who are non-compliant with testing and taking treatment regimens
- Patients who express problems with the treatment oils
- Women under the age of 14
- Women with a history of severe gynecological pathology; specifically, those with a diagnosis of endometriosis
- Subjects with severe co-morbid disease (cardiac, pulmonary, cancer, etc.); at the discretion of the medical team
- Subjects with alcohol abuse as determined by provider interviews

Confounding Factors:

- Age
- Gynecological history and related problems

Primary End-Points:

- Cramping
- Back and upper leg pain, discomfort, or cramps
- Abdominal tenderness (pain, GI upsets, nausea)
- Headaches
- Loss of appetite
- Dizziness
- General weakness
- Facial blemishes
- Emotional symptoms: depression, mood swings
- Recommend product

Analytical Methods:

Methods:

- Answers from survey tools were coded from 1 to 5
- Answers from the follow-up questionnaires were subtracted from each subjects' baseline data to create the outcome measures

Example:

Please write in the appropriate space, on the scale below, your rating for the symptoms below, for each day of your menstrual period, as they occur.

The answers were coded as follows,

Answer	***Code***
a. Not Present	*1*
b. Slightly	*2*
c. Moderately	*3*
d. Severely	*4*
e. Very severely	*5*

For example, a subject answering the question about cramps at baseline and final give the following answers corresponding to the subsequent codes,

Time	***Answer***	***Code***
Baseline	*d*	*4*
Final	*b*	*2*

The subtraction of the codes renders a point improvement for this subject on this question:

4 – 2 = 2 point improvement

- The answers for the two groups (placebo and treatment) for each symptom were collected and formed the basis of the results. One point differences have been classified as some improvement, while two point differences as significant, and three or four point improvements as dramatic.

    - No Improvement
    - Any Improvement: One point or greater
    - Some Improvement: Specifically one point improvement (minimally 20% improvement)
    - Significant Improvement: Specifically two points (minimally 40% improvement)
    - Dramatic Improvement: Specifically three or four point improvement (minimally 60% improvement)

- All categories were analyzed using the Chi-Square test. Some analyses used Fisher's Exact Two-Tail t-test, due to the small cell limitations. Fisher's is another type of chi-square test that must be utilized during scenarios of small cell sizes.
- These category improvements were determined a priori by the medical advisory group

Results:

Numbers:

Twenty-six (26) subjects completed the product phase of this trial while only fourteen (14) individuals completed the placebo phase of this trial. The numbers for the various outcomes, other than cramps, varied, since not all subjects experienced each different symptom at baseline. For example, a subject was enrolled as long as she experiences severe cramps, but she may not report any problems with headaches or abdominal distress.

Cramps:

All subjects reported on this outcome.

The efficacy of Menastil with respect to relief of menstrual cramping was demonstrated in that nearly eighty-one percent (80.8%) of the subjects taking the actual product reported some level of improvement in their symptoms while only fourteen percent (14.3%) of those on the placebo oil reported a similar level of relief. This difference was statistically significant at the 0.001 level.

Forty-two (42%) and thirty-one (31%) percent of the women on product reported a significant and dramatic improvement respectively on the product. Cumulatively, the significant level was the strongest level of response ($p < 0.000006$).

Leg and Backaches:

Twenty-four (24) and fourteen (14) subjects reported on this outcome.

The efficacy of Menastil with respect to relief of menstrual cramping was demonstrated in that seventy-two percent (72%) of the subjects taking the actual product reported some level of improvement in their symptoms while only twenty-one percent (21.4%) of those on the placebo oil reported a similar level of relief. This difference was highly statistically significant at the 0.000003 level.

Fifty-four (54.2%) and twelve percent (12.5%) of the women on product respectively reported a significant and dramatic improvement on the product. Cumulatively, the significant level was the strongest level of response (66.7% v. 0%, $p < 0.00005$).

Headaches:

Eighteen (18) and ten (10) subjects reported on this outcome.

The efficacy of Menastil with respect to relief of menstrual cramping was demonstrated in that seventy-two percent (72%) of the subjects taking the actual product reported some level of improvement in their symptoms while only ten percent (10.0%) of those on the placebo oil reported a similar level of relief. This difference was statistically significant at the 0.002 level.

Twenty-eight (28%) and five (5%) percent of the women on product reported a significant and dramatic improvement on the product. Cumulatively, the significant level was the strongest level of response (32 v. 0%, $p < 0.0009$ Fisher's).

Activities of Daily Living:

For any level of improvement, activities were improved for the women on product (67 v. 12%), while sleep was similarly improved (67 v. 8%), and work was improved (70 v. 16%).

For a significant level of improvement, the numbers for the three categories were fifty (50%), ten (10%), and fifty (50%) v. no responders for the placebo group.

Product Usage:

On average, one bottle of product was used for every two menstrual cycles in those women reporting success.

Adverse Events:

There were no adverse events reported in this trial. However, two women reported minor rashes, and two additional subjects reported "burning". All four subjects discontinued use and suffered no long-term effects.

Additionally, several women dropped the study because they felt the odor of the product was too strong for daily routine use.

Conclusions:

Clearly, Menastil is effective in relieving a number of common symptoms associated with severe menstrual cramping. These include cramps, back and upper leg aches, and headaches. Each of these symptoms was statistically different from those on placebo.

Additionally, several indicators of activities of daily living were improved using this product, including activities, sleep, and work.

It appears that Menastil is effective in relieving menstrual symptoms and improves ones' ability to function normally.

Based on this study, the safety of this product appears to be validated. Although, several women reported minor skin reactions involving rashes and a "burning" sensation, these left no effects after a day or two. We term these reactions minor in nature.

Marshall-Blum LLC
Menastil Intake Form

Date:___/__/___ ID#_____

First Name:_____Last Name_____

Address:_____

City:_____State:_____Zip _____

Phone(1): _____

Phone(2):_____

Message OK: ϒ Yes ϒ No

Email: _____

What will you be using this product for?

ϒ Menstrual Cramps

ϒ Regular Cramps

ϒ Aches and Pains

CONSENT TO BE A RESEARCH SUBJECT

NAME OF STUDY: Homeopathic Support for Menstrual Cramps, General Aches and General Pains: A Prospective, Randomized, Double-Masked Clinical Trial to Test the Efficacy and Short-Term Safety of Menastil™

STUDY INVESTIGATOR: James M. Blum, PhD
Marshall-Blum LLC
Herbal Research Clinic
268 State Street
Bangor, Maine 04401

207-990-4963

STUDY SPONSOR: Atlantic Management Resources
Westborough, Massachusetts

INTRODUCTION:

You are being asked to take part in a research study. Before you decide to take part in this study, you will need to know about the risks and benefits so that you can make an informed decision. This process is known as informed consent. This consent form provides information about the study.

Your decision to take part in this study is up to you. You are free to choose whether you want to be in the study or not. If you decide to take part in this study, you will be asked to sign this form. Federal law requires proof of your agreement to be in this study.

Please read this consent form carefully. Do not hesitate to ask questions as needed about any information or words you do not understand so that you can make an informed decision about being in the study or not.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test a homeopathic oil that is currently available on the market.

This study is designed to document the effectiveness (how well it works) and short-terms safety of Atlantic Management Resources' Menastil™ in relieving menstrual cramps, general aches and general pains.

Menastil™ contains: calendula, peppermint, rosemary, eucalyptus, orange, lemon and clary sage.

HOW LONG WILL I BE IN THE STUDY AND HOW MANY OTHERS ARE EXPECTED TO TAKE PART?

Your part in this study may last up to 2 weeks. About 30 people are expected to enroll for menstrual cramps. An additional 30 people are expected to enroll for general aches and general pains combined.

ARE THERE ANY CONDITIONS TO BE IN THE STUDY?

There are conditions to be in this study, some of which are dependent upon a determination made by the study investigator or study staff.

You may **not take part** in this study if:

- you are not compliant with the testing and treatment regimens;
- you express problems with the treatment ingredients;
- you are under the age of 14;
- you are between the ages of 14 and 18 and your parent or legal guardian will not sign this consent form;
- you are over the age of 70;
- you have diseases of a moderate to severe nature in any of your organ systems. The study nurse will go over the specific medical conditions that might exclude you from taking part in this study;
- you have a history of severe disorders of the female reproductive system. Specifically, a diagnosis of endomitriosis (abnormal tissure growth within the lining of the uterus), or fibroids (type of non-cancerous tumor) (if you are enrolling for menstrual cramps only);
- you have irregular menstrual cycles (if you are enrolling for menstrual cramps only)
- you are nursing, pregnant, or are trying to become pregnant;

Please inform the nurse of your full medical history and your allergies during the initial interview, including any medicines you are currently taking, so that she can decide if you meet all of the conditions to be in the study and to decide if there are any safety concerns about you taking part.

If you take any new medicine while in the study, please tell the nurse before you start so that she can decide if it is one that should be avoided.

WHAT WILL HAPPEN DURING THE STUDY?

First, you will be interviewed to help the study staff decide if you meet all of the conditions to be in the study.

You will have:

- questions asked about your medical history, including medications or herbal preparations you are currently taking;
- questions asked about your habits and living conditions;
- questions asked about your current condition and any treatments that you may have received.

Based upon this initial interview, if you qualify to take part in this study, you will be asked to sign this consent form if you agree to take part.
You will then

- be asked to complete a Demographic Questionnaire;
- be given instructions on how and when to complete the Questionnaires;
- be given a supply of your assigned product and the Questionnaires to be completed and mailed back.

You will be randomly assigned, similar to flipping a coin, to receive either active product or a placebo (contains no active ingredients). You have a 67% chance of being assigned to treatment with the active product. Neither you, the study investigator, nor the study nurse will know if you are being treated with the active product.

You will be instructed on how to take the homeopathic oil. Please refer to the instruction sheet provided for specific instructions.

You will be required to fill out the Questionnaires and mail them back to gather data and ensure compliance.

During this study, you will follow the enclosed instructions and mail back the enclosed questionnaires when you are finished.

This will be your only office visit and you will not be required to take any more study product after you mail back the questionnaires. Your participation in this study will end at that time.

WHAT ARE THE POSSIBLE RISKS OF THE STUDY?

There is always some chance that you will react to ingesting a new substance. However, the ingredients in this product have been well studied and the incidence of side effects is low.

There may be side effects that are not known at this time. You should inform the study staff immediately if you experience any side effects.

Please openly discuss with the study staff throughout this study your questions or concerns so that any and all issues can be dealt with properly and fully.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THE STUDY?

It is possible that you may find a way to permanently and successfully reduce your pain associated with menstrual cramps, general aches or general pains.

However, there is no guarantee you will benefit at all from taking the homeopathic oil.

WHOM SHOULD I CALL IF I HAVE QUESTIONS?

If a study related problem should occur, or if you have any questions at any time about the study, contact James M. Blum Ph.D., at Marshall-Blum LLC, 268 State Street, Bangor, ME 04401; phone: 1-207-990-4963.

ARE THERE OTHER OPTIONS I MAY CHOOSE?

You must view your part in this study as research and not providing routine treatment for pain from menstrual cramps, general aches and general pains.

There are other treatments available for these types of pain. You should consult your personal doctor about which available options are best for you.

HOW WILL THE INFORMATION COLLECTED BE KEPT PRIVATE?

Any information gathered for this project that can identify you will be kept strictly private. We at Marshall-Blum LLC take careful measures to protect patient privacy.

However, Marshall-Blum LLC may be required by law to make known certain records. It is possible that representatives of the United States Department of Health and Human Services, the United States Food and Drug Administration, Atlantic Management Resources or other federal or state government agencies may look at and/or copy your research records in the course of carrying out their duties. If your record is inspected or copied, Marshall-Blum LLC will use reasonable efforts to protect your privacy and the privacy of any medical information. Because of the need to release information to these parties, complete privacy cannot be promised.

The information gathered in this study may be published in scientific magazines, presented at scientific meetings, or used by Atlantic Management Resources in marketing this product, but your identity will not be revealed.

WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THE STUDY?

No provisions have been made for the treatment of injuries directly related to taking Atlantic Management Resources' Menastil™ or for payment of medical expenses for such treatment.

Atlantic Management Resources, the study sponsor, will not pay for treatment of pre-existing conditions or for any treatment of conditions arising after the study. Also, you will not receive money for wages because of lost time at your work place or due to any psychological stress.

This statement does not stop you from getting legal help.

WILL BEING IN THE STUDY COST ME ANYTHING?

All study related visits and study product will be provided to you at no cost.

CAN I REFUSE TO BE IN THE STUDY, QUIT LATER OR BE ASKED TO LEAVE THE STUDY?

Your decision to be in this study is up to you. You can choose not to take part in the study, or you can quit at any time. If you do not want to be in the study, or if you leave the study, there will be no punishment or loss of benefits.

If you wish to leave the study, please tell the study investigator or study nurse.

The study investigator, James M. Blum, PhD, or Atlantic Management Resources, the study sponsor, may stop this study, or you being a part of it at any time for any reason without your consent. If this happens, it might be for any of the following reasons:

- You have a bad reaction to the active product
- The study is canceled
- You do not follow the study directions

The study investigator will also tell you about any new information learned during the course of this study that might cause you to change your mind about taking part in the study.

FINANCIAL DISCLOSURE:

The persons conducting the research and/or the institution will be paid for subject enrollment, record keeping, administrative services, and any other customary research services provided. You are free to ask about this payment.

AGREEMENT TO BE IN THE STUDY:

To become a part of this study, you or your legally authorized representative must sign this consent form. By signing this consent form you are confirming the following:

- All oral and written information and discussions about the study were in a language that you understood.
- The purpose and nature of the study, its expected length, the procedures that will be done, all reasonable foreseeable risks and discomforts, and benefits were explained to you and you had time to think about them.
- All of your questions have been answered to your satisfaction. If you did not understand any of the words, you asked the study investigator or a staff member to explain them to you.
- You freely agree to be part of this study, to follow the study directions, and to provide necessary information to the staff members, as requested.
- You know that you may freely choose to stop being a part of this study at any time without having to give a reason and without affecting your medical care.
- You know that by signing this consent form you are not giving up any legal rights you may have as a participant in a research study.

_____
Volunteer's Name (Printed)

Please write in the date when you sign your name.

_____ _____
Signature of **Volunteer** or **Authorized Representative** Date

_____ _____
Signature of **Person Actually Explaining Consent** Date

_____ _____
Signature of **Study Investigator** (if not sign above) Date

_____ _____
Signature of **Impartial Witness** Date
(if person giving the consent cannot read)

You will receive a signed copy of this consent form to keep for yourself.

Demographic Form
Marshall-Blum, LLC

Study: _____

Date:____/____/____ ID#: _____

This survey asks you general demographic questions. It is intended to give us a snapshot of the population that is in this study. All information is strictly confidential and is presented in a cumulative summarized form. We greatly appreciate your help and cooperation in this matter.

Please answer every question by marking one box. If you are unsure about an answer, please give the best answer you can. If you feel uncomfortable answering a question, please skip that question and move to the next one.

1. Please select the appropriate gender category: 1. ⑨ Male 2. ⑨ Female

2. Your current age is:_____years

3. Please select your ethnic origin:
1. ⑨ Asian or Pacific Islander
2. ⑨ Black
3. ⑨ Hispanic
4. ⑨ Native American or Alaskan Native
5. ⑨ White
6. ⑨ Other, please specify: _____

4. **Your current weight is approximately:**_____pounds

5. **Your height is approximately: (feet and inches):**_____ft /_____inches

6. Please indicate the category that best describes your current occupation/homemaking status:
1. ⑨ clerical 2. ⑨ craftsperson/technical 3. ⑨ homemaker 4. ⑨ management
5. ⑨ military 6. ⑨ professional 7. ⑨ retired 8. ⑨ self-employed
9. ⑨ service industry 10. ⑨ student 11. ⑨ teaching 12. ⑨ not working
12. ⑨ Details or Other, please specify: _____

7. In the above mentioned jobs / duties, do you work:
1. ⑨ 36 hours or More
2. ⑨ Less than 36 hours
3. ⑨ Not Applicable

8. Please indicate the category that best represents your total annual household income (all sources), before taxes:
1. ⑨ Under $20,000
2. ⑨ $20,000 and under $40,000
3. ⑨ $40,000 and under $60,000
4. ⑨ $60,000 and under $80,0000
5. ⑨ $80,000 and under $100,000
6. ⑨ $100,000 and above

Continued on back

9. Including yourself, how many adults live in your household (18 years old or Over)?
1. ⑨ 1 2. ⑨ 2 3. ⑨ 3 4. ⑨ 4 5. ⑨ 5-6 6. ⑨ 7 or more

10. How many people under 18 years old live in your household?
1. ⑨ 0 2. ⑨ 1 3. ⑨ 2 4. ⑨ 3 5. ⑨ 4 6. ⑨ 5 or more

11. Please indicate the highest level of education that you have achieved?
1. ⑨ Did not graduate from High School
2. ⑨ Graduated High School
3. ⑨ Some college or vocational training or Associate Degree
4. ⑨ Bachelor Degree and/or Some-Post-Graduate
5. ⑨ Graduate Degree
6. ⑨ Doctorate or Professional Degree

12. Please indicate your current smoking status?
0. ⑨ I have never smoked
1. ⑨ No, I quit in the last two years
2. ⑨ No, I quit more than two years ago
3. ⑨ Yes, I smoke less than 1 pack a day
4. ⑨ Yes, I smoke one pack or more a day

13. **If an alcoholic drink is defined as: one bottle/can of beer <u>equals</u> one glass of wine <u>equals</u> one ounce of hard liquor**, ***how may drinks do you consume in an average week:***
0. ⑨ None 1. ⑨ average less than 1 2. ⑨ 1- 2 3. ⑨ 3-4 4. ⑨ 5-6 5. ⑨ 7-8
6. ⑨ 9-10 7. ⑨ more than 10

14. How many times each week do you exercise?
1. ⑨ Less than 1 2. ⑨ 1-2 3. ⑨ 3-4 4. ⑨ 5-6
5. ⑨ 7-8 6. ⑨ 9 or more

15. In general, would you say your health is:
1. ⑨ Excellent 2. ⑨ Very Good 3. ⑨ Good 4. ⑨ Fair 5. ⑨ Poor

16. Do you use vitamin supplements?
1. ⑨ Yes 0. ⑨ No 2. ⑨ Sometimes

17. Do you use herbal supplements?
1. ⑨ Yes 0. ⑨ No 2. ⑨ Sometimes

18. Do you use any non-physician practitioners for your medical care?
1. ⑨ Yes 0. ⑨ No 2. ⑨ Sometimes

END – Thank you for your participation

Menstrual Survey
Symptom Severity Scale Items and Applicable SF36 Questions
Marshall-Blum, LLC

Date:____/____/____ ID#: _____

Directions: Please write in the appropriate space, on the scale below, your rating for the 12 symptoms before each time (episode) that you use the oil and within (1) one hour after using the oil.

1 = Not Present 2 = Slight 3 = Moderate 4 = Severe 5 = Very Severe

Symptom:	***Episode 1***		***Episode 2***		***Episode 3***		***Episode 4***	
	Pre	***Post***	***Pre***	***Post***	***Pre***	***Post***	***Pre***	***Post***
1. Cramps								
2. Abdominal pain								
3. Nausea / Vomiting								
4. Diarrhea								
5. Headache								
6. Backache								
7. Leg ache								
8. General aching								
9. Dizziness								
10. Weakness								
11. Depression								
12. Irritability / Mood Swings								

For the following questions, please tell us how much your menstrual period limits your level of participation in the following activities at the same times as above. Please use the following scale.

1=No limitations 2=Minor limitations 3=Substantial limitations 4=Severe limitations
5=Not able to participate in the activity

Limitations secondary to menstrual discomfort:	***Episode 1***		***Episode 2***		***Episode 3***		***Episode 4***	
16. Moderate activities*	***Pre***	***Post***	***Pre***	***Post***	***Pre***	***Post***	***Pre***	***Post***
17. Sleep								
18. ADL**								
19. Work/School								

**Moderate activities include moving a table, pushing a vacuum cleaner, bowling, or playing golf.*
***ADL=Activities of Daily Living (example: eating, bathing, getting dressed)*

Menastil Satisfaction Questionaire
Marshall-Blum LLC

Fill this out after you have used the Menastil product for both episodes.

1. How do you feel about the effectiveness of the product you've been taking?
   1.very positive 2. positive 3. neutral 4. negative 5. very negative

2. Would you recommend this product to a friend?
   1. yes 0. no 2. not certain

3. Have you used products for a similar purpose?
   1. yes 0. no

   If yes how does this product compare?_____

4. How pleasant was the fragrance or odor of the product?
   1. very pleasant 2. pleasant 3. neutral 4. unpleasant 5. very unpleasant

5. How easy is it to use the product?
   1. very easy 2. easy 3. neutral 4. difficult 5. very difficult

6. How do you feel about the oil application of the product?
   1. I like the oil application 3. I don't like it
   2. It's OK 4. I really don't like it

If you didn't like the oil application, how would you change it?

_____

_____

7. Have you noticed any unexpected effects from the product?

_____

Is there anything else you would like to tell us about your use of this product?

_____

_____

_____

Thank you for completing this survey.

BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

Prospective, Randomized, Double-Blind Placebo-Controlled, Clinical Trial Results as of:

January 4, 2002

Claire Ellen Products

BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

Explanations

p-Value

$p < 0.05$ Confirms that the difference between product and placebo are statistically significant

Fisher's

A p-Value test that is used when there is a small sample size

BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

Explanation

Cumulative

Concept of additive parts.

For example; “Some” includes subjects reporting some or significant or dramatic results.

For “significant”, this includes subjects with significant or dramatic results.

BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

Cumulative

Key: Reduction of Menstrual Cramps

Placebo; (n=14): 14 subjects completed the placebo phase
Product; (n=26): 26 subjects completed the product phase

Some	=	1 or more points
Significant	=	2 or more points
Dramatic	=	3 or more points

* 5-Point Scale
* 4- Point Improvement = Max Possible
* Based on Initial Response

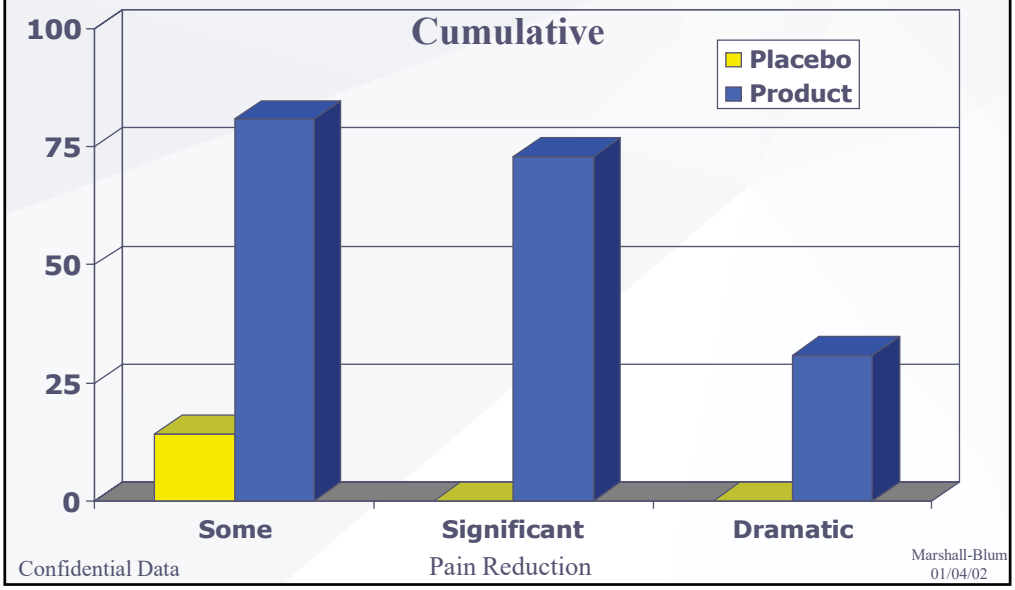
BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

Menstrual Cramps

Reduction of Menstrual Cramps (5-Point Scale)



Confidential Data

Marshall-Blum
01/04/02

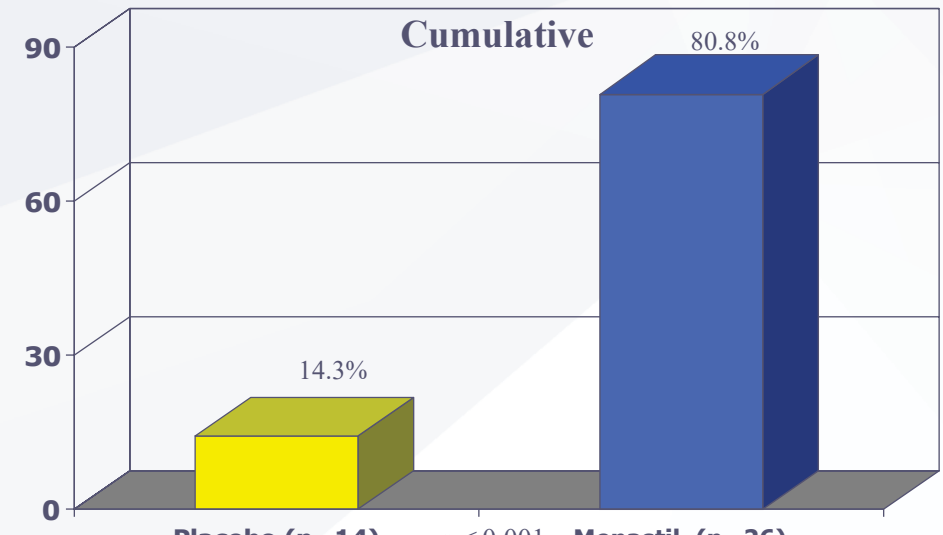
BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

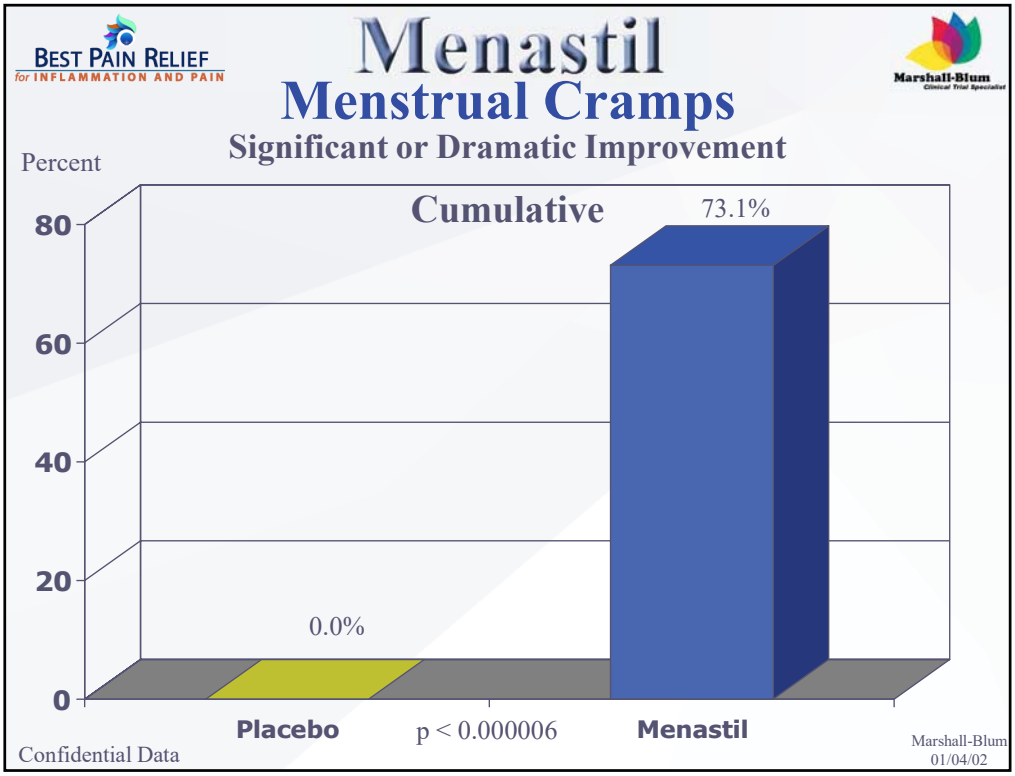
Menstrual Cramps

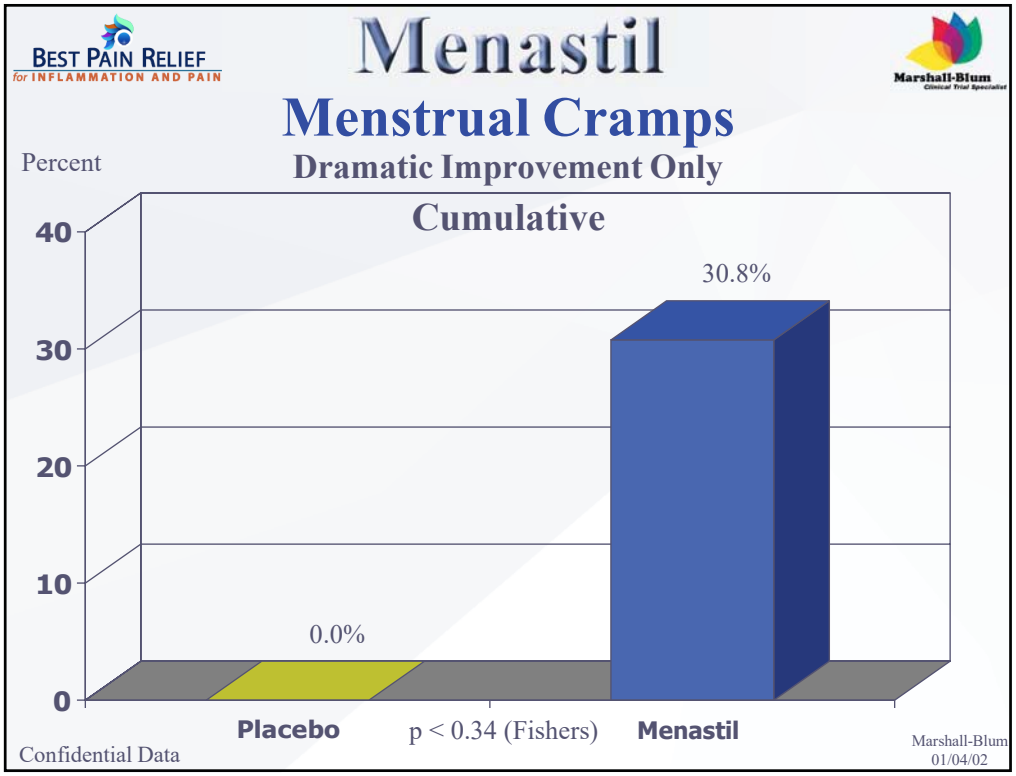
Some or Significant or Dramatic Improvement



Confidential Data

Marshall-Blum
01/04/02


BEST PAIN RELIEF
for INFLAMMATION AND PAIN
Menastil
Menstrual Cramps
Significant or Dramatic Improvement
Marshall-Blum
Percent
Cumulative
73.1%
80
60
40
20
0
0.0%
Placebo
p < 0.000006
Menastil
Confidential Data
Marshall-Blum
01/04/02


BEST PAIN RELIEF
for INFLAMMATION AND PAIN
Menastil
Menstrual Cramps
Dramatic Improvement Only
Marshall-Blum
Percent
Cumulative
40
30
20
10
0
30.8%
0.0%
Placebo
p < 0.34 (Fishers)
Menastil
Confidential Data
Marshall-Blum
01/04/02

BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

Cumulative

Key: Reduction of Backache

Placebo; (n=14): 14 subjects completed the placebo phase
Product; (n=24): 24 subjects completed the product phase

Some	=	1 or more points
Significant	=	2 or more points
Dramatic	=	3 or more points

* 5-Point Scale
* 4- Point Improvement = Max Possible
* Based on Initial Response

Confidential Data

Marshall-Blum
01/04/02

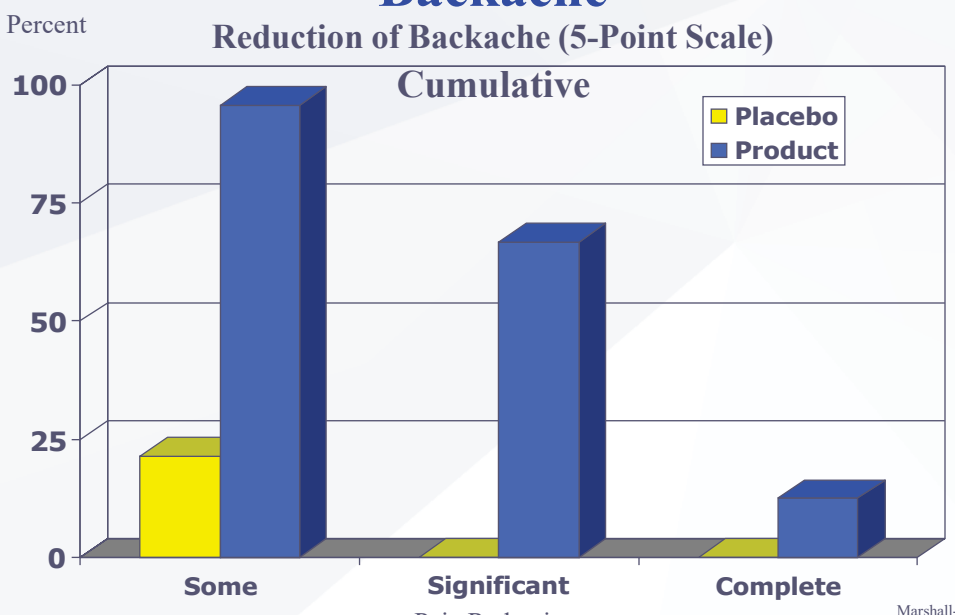
BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

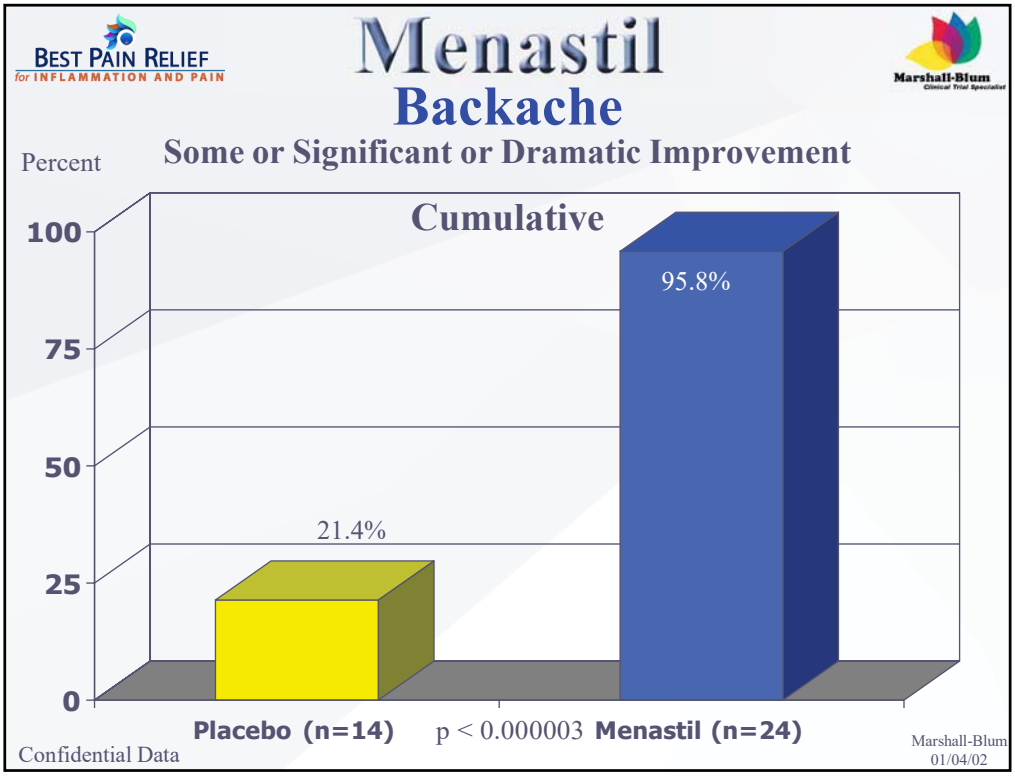
Backache

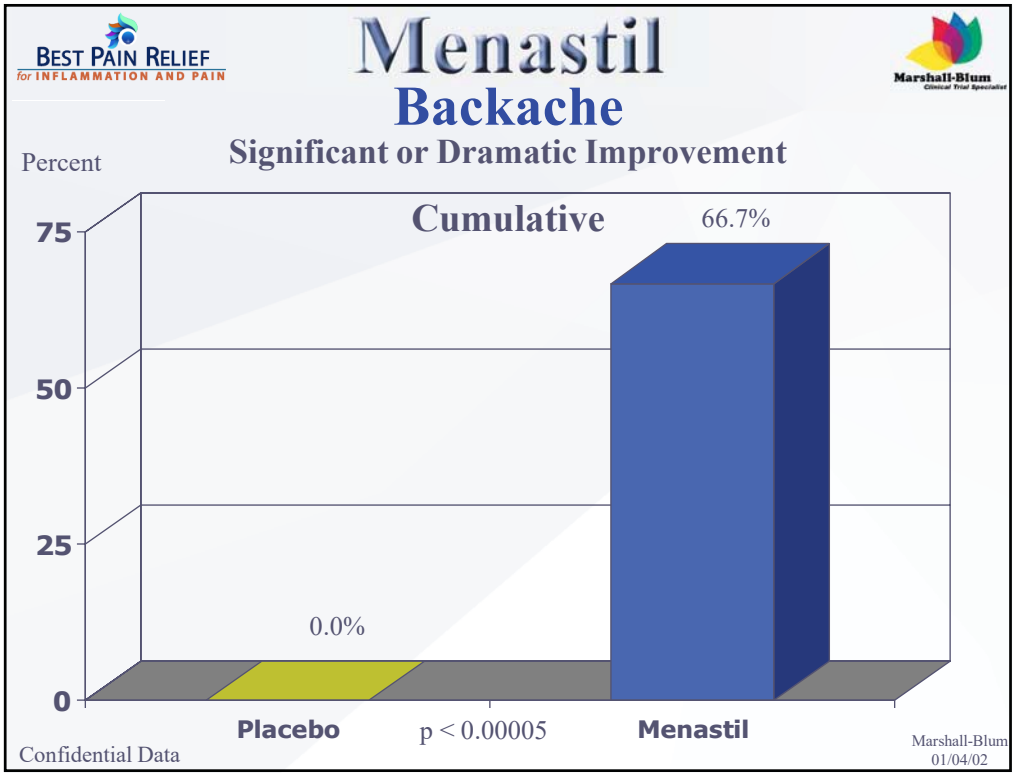
Reduction of Backache (5-Point Scale)



Confidential Data

Marshall-Blum
01/04/02


BEST PAIN RELIEF
for INFLAMMATION AND PAIN
Menastil
Backache
Some or Significant or Dramatic Improvement
Marshall-Blum
Percent
Cumulative
100
75
50
25
0
95.8%
21.4%
Placebo (n=14)
p < 0.000003
Menastil (n=24)
Confidential Data
Marshall-Blum
01/04/02


BEST PAIN RELIEF
for INFLAMMATION AND PAIN
Menastil
Backache
Significant or Dramatic Improvement
Marshall-Blum
Percent
Cumulative
75
50
25
0
66.7%
0.0%
Placebo
p < 0.00005
Menastil
Confidential Data
Marshall-Blum
01/04/02

BEST PAIN RELIEF for INFLAMMATION AND PAIN

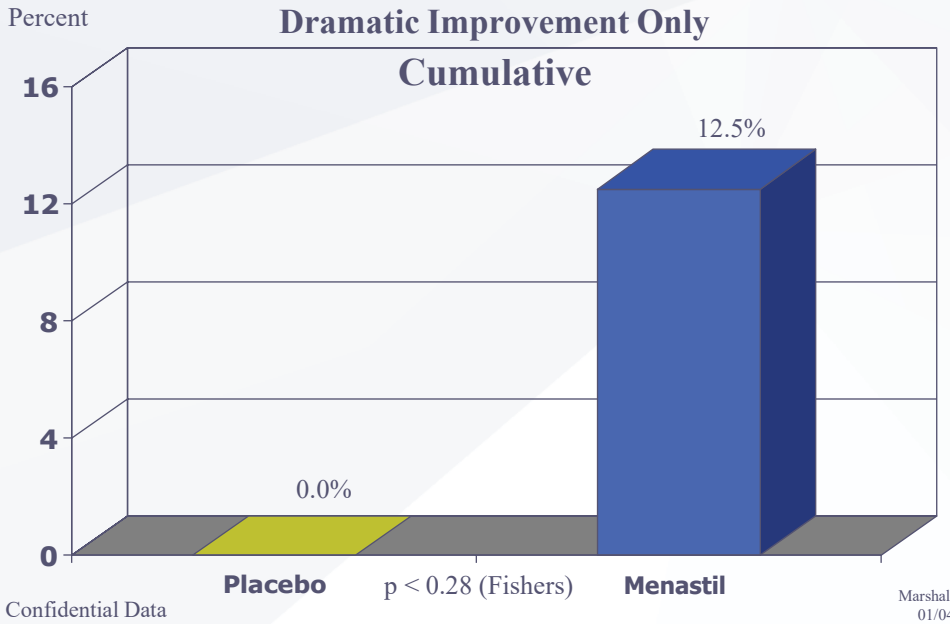
Menastil

Marshall-Blum Clinical Trial Specialist

Backache

Dramatic Improvement Only

Cumulative



Confidential Data

Marshall-Blum
01/04/02

BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

Cumulative

Key: Reduction of Headache

Placebo; (n=10): 10 subjects completed the placebo phase
Product; (n=18): 18 subjects completed the product phase

Some	=	1 or more points
Significant	=	2 or more points
Dramatic	=	3 or more points

* 5-Point Scale
* 4- Point Improvement = Max Possible
* Based on Initial Response

Confidential Data

Marshall-Blum
01/04/02

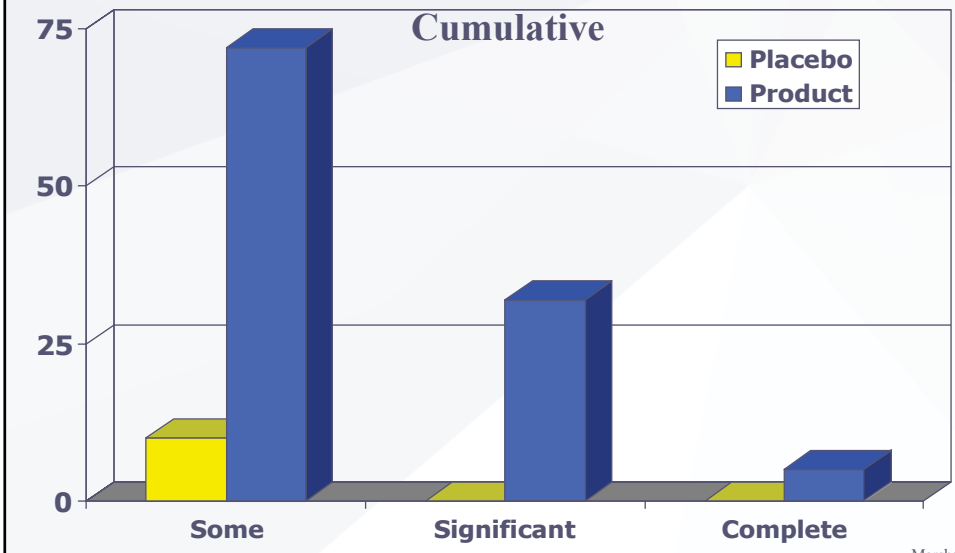
BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

Headache

Reduction of Headache (5-Point Scale)



Confidential Data

Marshall-Blum 01/04/02

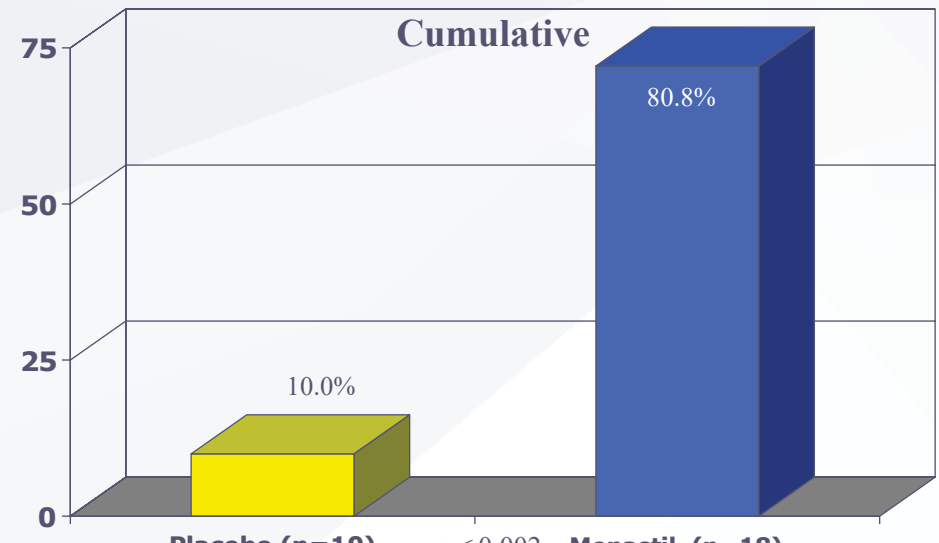
BEST PAIN RELIEF for INFLAMMATION AND PAIN

Menastil

Marshall-Blum Clinical Trial Specialist

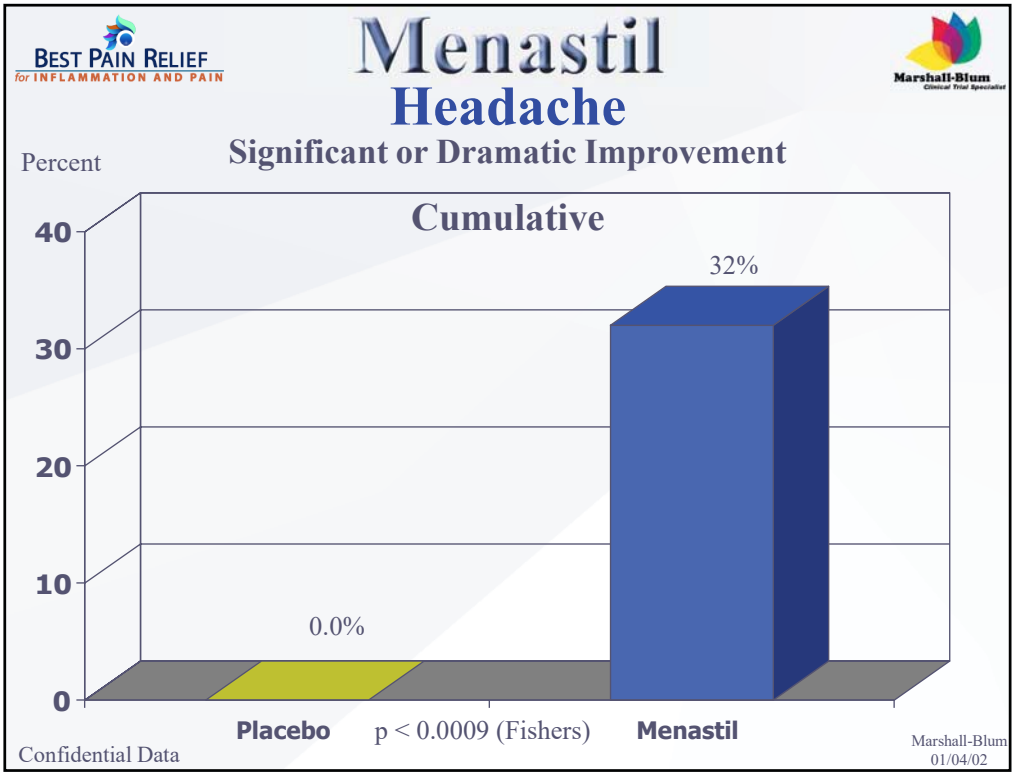
Headache

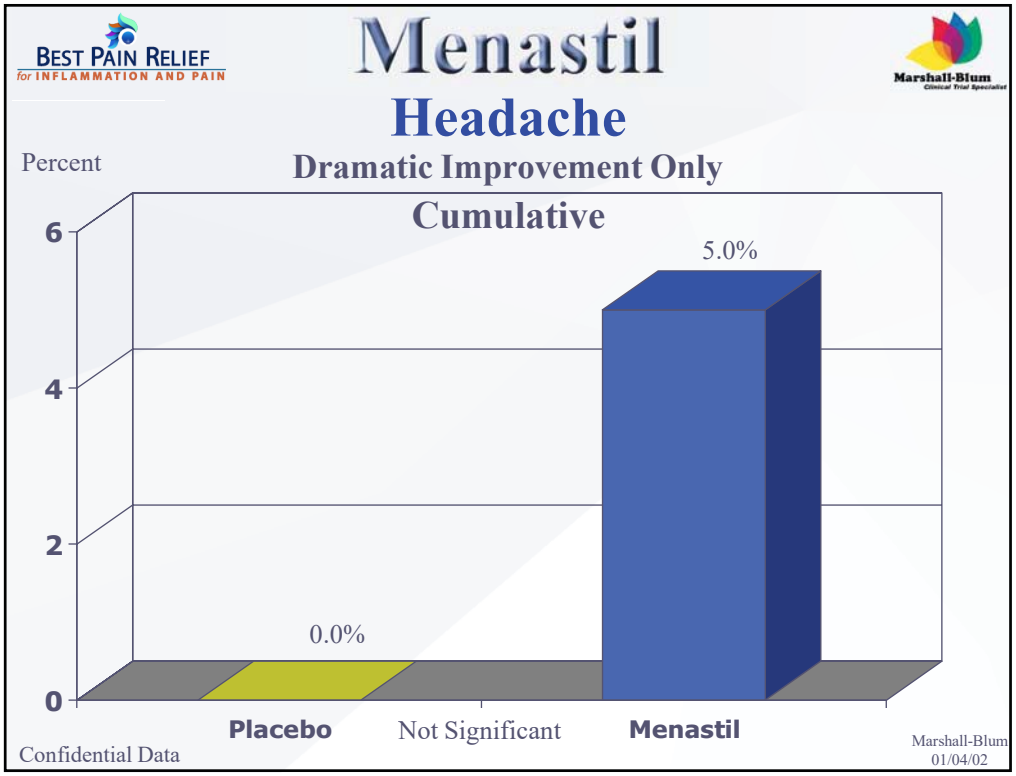
Some or Significant or Dramatic Improvement

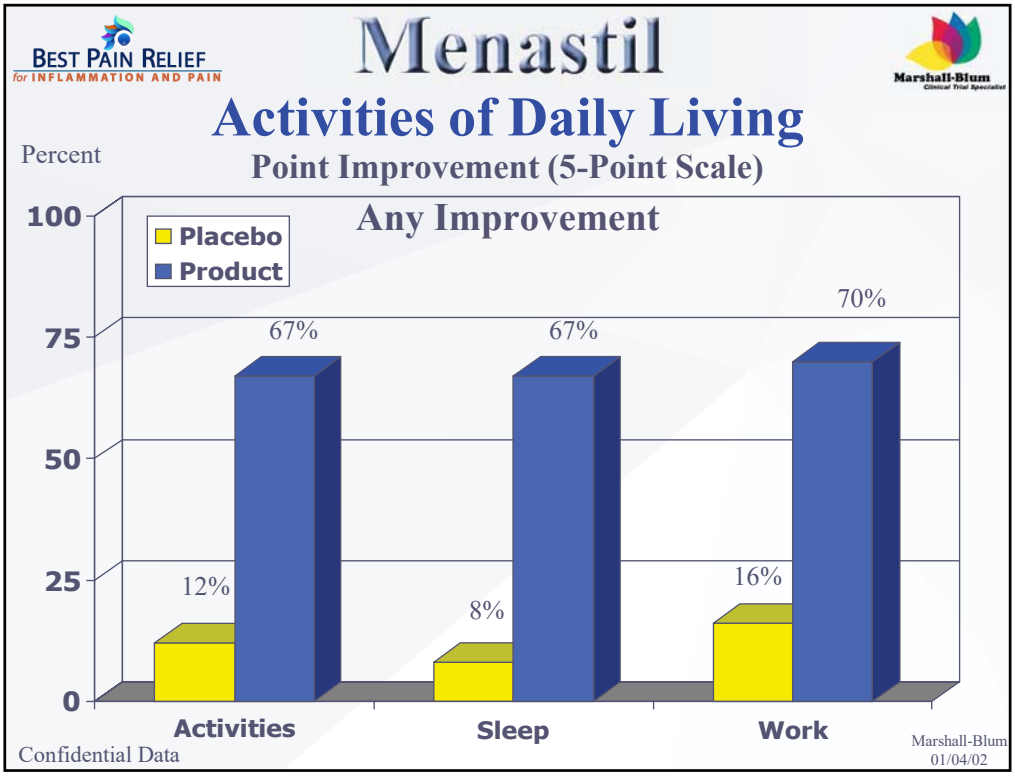


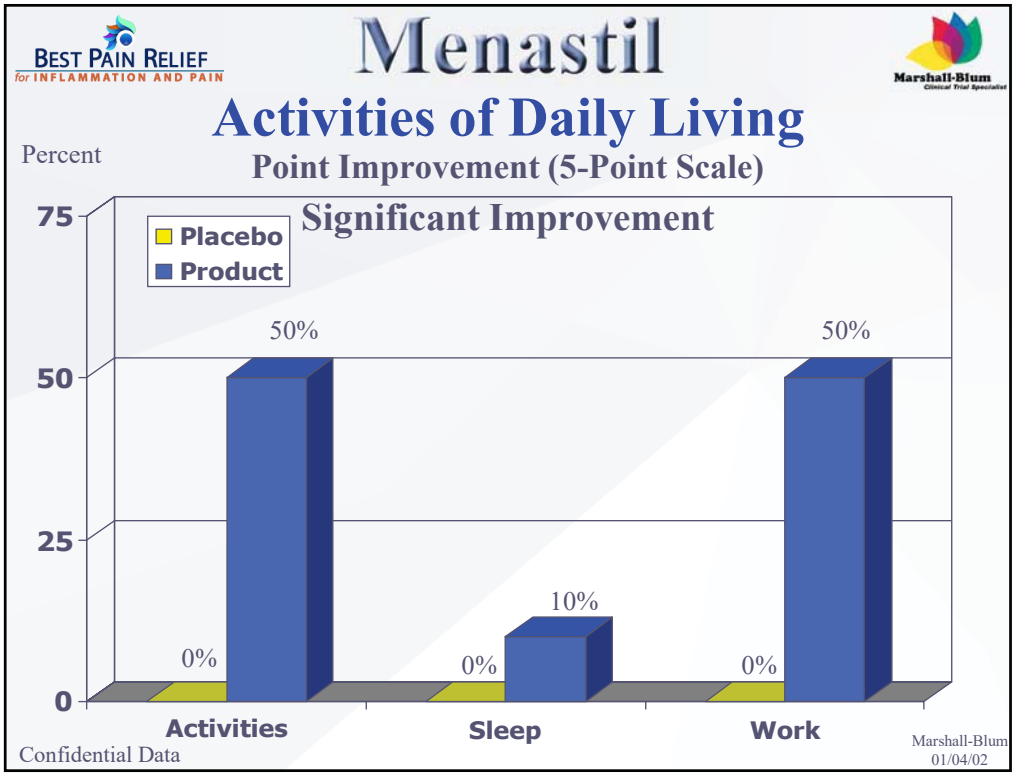
Confidential Data

Marshall-Blum 01/04/02


BEST PAIN RELIEF
for INFLAMMATION AND PAIN
Menastil
Headache
Marshall-Blum
Clinical Trial Specialist
Significant or Dramatic Improvement
Percent
Cumulative
40
30
20
10
0
32%
0.0%
Placebo
p < 0.0009 (Fishers)
Menastil
Confidential Data
Marshall-Blum
01/04/02


BEST PAIN RELIEF
for INFLAMMATION AND PAIN
Menastil
Headache
Marshall-Blum
Clinical Trial Specialist
Dramatic Improvement Only
Percent
Cumulative
6
4
2
0
5.0%
0.0%
Placebo
Not Significant
Menastil
Confidential Data
Marshall-Blum
01/04/02


BEST PAIN RELIEF
for INFLAMMATION AND PAIN
Menastil
Marshall-Blum
Activities of Daily Living
Point Improvement (5-Point Scale)
Percent
Any Improvement
Placebo
Product
100
75
50
25
0
67%
67%
70%
12%
8%
16%
Activities
Sleep
Work
Confidential Data
Marshall-Blum
01/04/02


BEST PAIN RELIEF
for INFLAMMATION AND PAIN
Menastil
Marshall-Blum
Activities of Daily Living
Point Improvement (5-Point Scale)
Percent
Significant Improvement
Placebo
Product
75
50
25
0
50%
50%
10%
0%
0%
0%
Activities
Sleep
Work
Confidential Data
Marshall-Blum
01/04/02

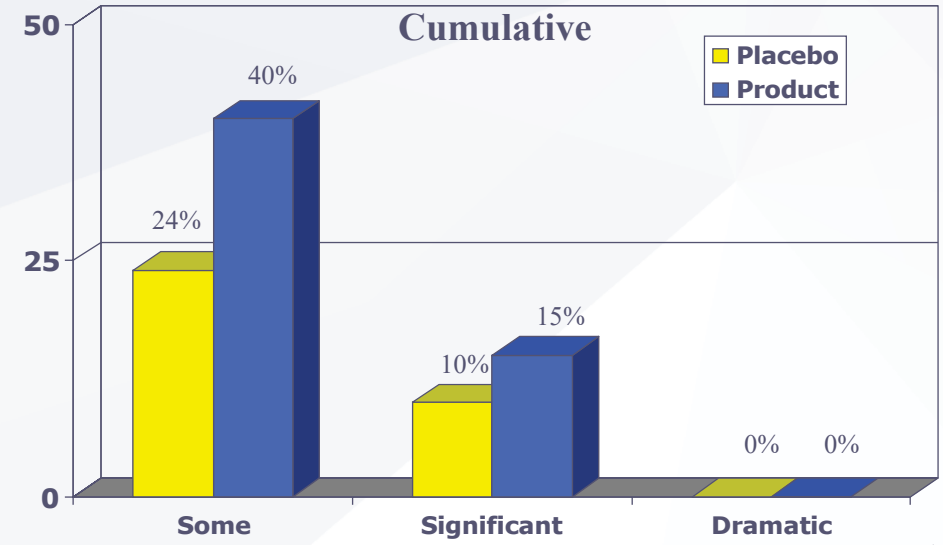
BEST PAIN RELIEF
for INFLAMMATION AND PAIN

Menastil

Marshall-Blum
Clinical Trial Specialist

Leg Aches

Reduction of Menstrual Cramps (5-Point Scale)



Confidential Data

Marshall-Blum
01/04/02

Marshall-Blum LLC
Mcol.stil lmake Fonn

Date [redacted] ID# [redacted]

First Name [redacted] Last Name [redacted]

Address [redacted]

City: [redacted] Sune _ Zip -

Pho11e(l) • [redacted]

Phone(2 _____

MessageO K X' Yes No

F.maJI [redacted]

Wha1 wilJ you be using 1his r rod uc1 *for'.1*

>(Menstrual Crnmps

Rcgulitr Cramps

Aches and Pams

HO W LO NG WILL I BE IN THESTUDY AND HOW MANY OTHERS ARE EXPECTED TO TAKE PART?

Your partIn lhis study *may* last up to 2 weeks. About 30 people are expected 10 enro ll for menstrual cramps An addrtlonal 30 people are expected to enroll for general aches and general pains combined.

ARE THERE ANY CONDITIONS TO BE IN THE STUDY?

There are conditions to be on lh i s s tu d y, some of which are dependent upon a determination madeby the study investigator or study staff.

You *may* not **take part** in this study lf:

- you are not compliant with the Jest ing an d trea tme nt regimens ,
- you express problems with the treatment ingredients:
- , *you* are under the age of 14;
- *you* are between the ages of 14 and 18 and your parent or legal guardian will not sign this consent form:
- **you are over 1he age of 70,**
- *you* have diseases of a moderate to severe nature In *any* of your organ systems The study nurse will go over the specific medical conditions that might exclude you from taking part in this study;
- , you have a history of severe disorders of the female reproductive system Specrfically, a diagnos s or endomitriosis (abnormal tissure growth within the linmg of the uterus), or fibroids (type of non-canceroustumor) (if you are enrolhng **for menstrual cramps onl y);**
- you hav,e rregular menstrual cycles(if you are enrolling for menstrual cramps only)
- *you* are nursing, pregnanl or are trying to become pregnant;

Please inform the nurse of your full medical history and your allergies during the m11a lnterview , in cludi ng *any* med icine s you are curr en tly tak in,g so that she can decide if **you meet all of the conditions to be in the study and to decide lf there are any safety** concern s abo ut you lak ing part.

If you lake any new medicine while in the study, please tell the nurse before you start so that she can decid,e f ii is one that should be avoided.

WHAT WILL HAPPEN DURING THE STUDY?

Fust, you will be Interviewedto help the study staff decide if you meet all of the **cond1bons to be m the study,**

You will have:

- questions asked about your medical history, including medications or herbal preparations you are currently taking;
- questions asked about your habits and living conditions;
- questions asked about your current condition and any treatments that youmay have received.

Based upon thisinitial Interview, ff you qualify to takepart in this study, you will be asked to sign lhis consent form if you agree to takepart
You will then

- be asked to complete a Demographic Questionnaire;
- be given fnstructions on how and when to complete the Questionnaries;
- be given a supply of your assigned product and the Questionnaires 10 be completed and mailed back.

You will be randomly assigned similar to nipping a coin, to receive either active product or a placebo (contains no active ingredients). You have a 67% chance of being assigned to treatment with the active product. Neither you, the study investigator, nor the study nurse will knowii you are being treated with the active product.

You will be instructed on how to take the homeopathic oil. Please refer to the instruction sheet provided for specific ins truction.s

You will be required to filloutthe Questionnaires and mail them back to gather data and ensure compliance.

Dunng this study, you will follow the enclosedinstructions and mail back the enclosed questionnaireswhen you are finished.

This will be your only office vistt and you will not be requiredto take any more study product after you mail back the questionnaires. Your participation In this study willend al that time

WHAT ARE THE POSSIBLE RISKS OF THE STUDY?

There is always somechance that you will react to ingesting a new substance. However, the ingredients in this product havebeen well studied and the Incidence of side effects is row.

There *may* be side effects that are not knownat this time. You should inform the study staff immediately if you experience any side effects.

Please openly discuss with the study staff throughout this study your questions or concerns so that *any* and all issues can be dealt with properly and fully

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THE STUDY?

It is possible that you may find a way to permanently and successfully reduce your pain **associated with menstrual cramps, general aches or general pains.**

However there is no guarantee you will be benefit at all from taking the homeopathic oil.

WHOM SHOULD I CALL IF I HAVE QUESTIONS?

If a study related problem should occur, or if you have *any* questions at any time about the study contact James M. Blum Ph.D., at Marshall-Blum LLC, 268 State Street, Bangor, ME 04401; phone: 1-207-990-4963.

ARE THERE OTHER OPTIONS I MAY CHOOSE?

You must view your part in this study as research and not providing routine treatment **for pain from menstrual cramps, general aches and general pains.**

There are other treatments available for these types of pain. You should consult your personal doctor about which available options are best for you.

HOW WILL THE INFORMATION COLLECTED BE KEPT PRIVATE?

Any Information gathered for this project that can identify *you* will be kept strictly private. We at Marshall-Blum LLC take careful measures to protect patient privacy.

However Marshall-Blum LLC may be required by law to make known certain records. It is possible that representatives of the United States Department of Health and Human Services, the United States Food and Drug Administration, Atlantic Management Resources or other federal or state government agencies may look at and/or copy your **research records in the course of carrying out their duties. If your records is inspected or** copied Marshall-Blum LLC will use reasonable efforts to protect *your* privacy and the privacy of any medical information. Because of the need to release information to these parties, complete privacy cannot be promised.

The information gathered in this study *may* be published in scientific magazines, presented at scientific meetings, or used by Atlantic Management Resources in marketing this product. but your identity will not be revealed.

WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THE STUDY?

No provisions have been made for the treatment of injuries directly related to taking Atlantic Management Resources' Menastil™ or for payment of medical expenses for such treatment.

Atlantic Management Resources, the study sponsor, will not pay for treatment of pre-existing conditions or for any treatment of conditions arising after the study. Also, you will not receive money for wages because of lost time at your work place or due to any psychological stress.

This statement does not stop you from getting legal help.

WILL BEING IN THE STUDY COST ME ANYTHING?

All study related visits and study product will be provided to you al no cost.

CANI REFUSE TO BE IN THE STUDY, QUIT LATER OR BE ASKED TO LEAVE THE STUDY?

Your decision to be in this study is up to you. You can choose not to lake part in the study, or you can quit at any time. If you do not want to be in the study, or if you lea ve the study, there will be no punishment or loss ol benefits

If you wish to leave tho study, please toll thestudy investigator or study nurse.

The study investigator, James **M**. Blum. PhD, or Atlanhc Management Resources, the study sponsor. may stop this study, or you being a part of it at any tune for any reason w th out your consent. If this happens, it might be for any of the following reasons:

- You have a bad reaction to the aehve product
- The study Is canceled
- You do not follow the study directions

The study investigator w,11also tell you about any new information leamed during the course of th,s study that might cause you to change your mind about taking part in the study.

FINANCIAL DISCLOSURE:

The persons conducting the research and/or the Institution will be paid for sub ject enrollment, record keeping, administrative services, and any other customary research services provided. You are free to ask about this payment.

AGREEMENT TO BE IN THE STUDY:

To become a part of this study, you or your legally authorized representalive must sign lhis consenl form. By signing lhis consent form you are confirming the following

- All oral and written information and discussions aboullhe study were in a language thal youunderstood.
- The purpose and nalure of the sludy, its expected length, the procedures thatwill **be done, all reasonable foreseeable risks and discomforts. and benefi1s were** explained 10 you and you had time 10 lhink aboul them.
- All of your ques1lons have been answered to your sallsfacbon If you did not undersland any of lhe words, you asked the sludyinvesligatoror a staff member to explain them to you.
- You freely agree to be part of this study, to follow the study directions, and to provide necessary information 10 the staff members, **as** requested.
- You know thalyoumay freely choose to stop being a part of this study al any time wilhoul having to give **a** reason and without affecting your medica.l care
- Youknow lhat by signing lhis consenl form you are no1giving up any legal rights **you may have as a participant in a research study**

[redacted]
Volunteer's Name (Printed)

Please write in tho date when you sign your name

[redacted]
Signature of **Volunteer** or **Authorized Representative**

[redacted]
Date

[redacted]
Signature of **Person Actually Explaining Consent**

[redacted]
Date

Signature of Study Investigator

Date

Signatureof Impartial Witness

Date

You will receive a signed copy of this consent form to keep for yourself.

Volunteer's Initials [redacted]

Oemognphic Funn
M•nhall-Blum, LLC

Study: Mcns:h»o.l c coo,ps

Date: [redacted] ID#: [redacted]

Thissurveyasksyou general demographic questions. h i-' intended to give u $ a s naps hot of the popufation 1bat is in this study. All infomuuion is stric. 1) confid t n tiaJ and *is* p rese n u:<I ln a c um ulativ e s u mrna riud form. We greatly appreciate your help and cooptn1tioo in this matter.

P ase answer ,e, ery qu1.-slion by marking one box. lf you are unsun about an an.s"' t r, (>lt lu c give the be s t answer you can. If you fetl uneomfortable answering a question, please ski-1 that question a nd move to tht." nut o ne.

I. Pleas.e elrc t Ch e appropriate gender c:ategory: 1. ☐ Mole 2. IB"remale

2. Your curre nl age L°': /g years

.:l. Plc:1se select your t1hnlt origin:
10 Asjan or P ci.6c Is lander
2. ☐ Black
3. ☐ Hispanic
4. ☐ Native Ame.rican or AJusklUl Native
S.G!'Wbite
6. ☐ O ther , pletl:;C s pec ify: _ _ _ _ _ _ _

4. Your curre111 weight is approximately: _.,1,.3ea5,_ pounds

S. Your he-ight l5approximately: (feet sand inches): c ft / 7 UlOheS

6. Pl e as e indicate the e.alegory that bes1des.tribes your current orcuparlo n/h om ma kin g status:

l. ☐clerical 2.☐craftspersonltechnicnl 3. ☐ hcunemaker 4. ☐ ruanag:emen1
5.☐military 6.☐ professional 7. ☐retired 8. ☐ self-employed
9. ☐ se rvice induSll)' 10. 10 stu Klen t 11. ☐ ieacJung 12. ☐not working
12.☐ Dern.Us ot Ot hcr, plea:::;e spcci(y: _

7. In the abovt mention1.-d job s / dutie.t, do you work:
I. ☐J6 hqurs or More
2. ☐ Less1han 36 *hours*
3. ill'Not Applicable

8. Ple.ase indkare the category that best reprc.,cot, your totaJ annual household in(omt (all sources), be.fore tan ,:
l. ☐ Under S20.000
2.☐$20,000 and under**S40,000**
3. 13'$40.000 nnd under **560,000**
4. ☐ $60.000 and under$80,0000
5. ☐ $80,000 ood underS I00,000
6. ☐$100,000 and above

Co11ti1tued on back

9. In rlud ing yuu r.,ic.lf, how m1ny Qdult!live io your household (18 yea rs old or Ovt rf!

1.0 1 2. 111'2 3.0 3 4. ☐ 4 S. ☐ S-6 6. ☐ 7 or m◇n:

I0. I low many people undl'r 18 yt>ars old live in your hnusebold'!

100 I 3 .☐2 4. 0 3 5. 6. CJ Sor more

11. Please indicate the highest lc, ·t'l of educalion tbal you ha, ·e achie, •W'!

I. ☐ Did oo1 !lfflluiue from Hig), School

- GifGraduni<d HighSchool

3. ☐ Some college o r vocational training or Associmc Degree

4. Q 13ach d o r Degree and/orSome-Pos1-Gradua1c

S. ☐ Gcddwu, D<-gr«

6. ☐ Doc to ra te ur Pn.1ef:;sionalDegree

12. Please indic-ai e yourcurre.nt smoking statu,S?

0. lkl"I havene,et :i.inohd

I.0 No. I qui'I in1hc lasl IWOyears

2. ☐ No. I t.1ui 1 more th;in two years ago

3 ☐ Yes. I smoke lessthan I pack uday

40 Yes. I smoke onepiltk or mon:: u day

I3. If :rn ukobolk drink is ddintd as: onebottle-1ea n of beer egual,i; one gls or wine en u:il.; On t' uuuct' of han,I Uq uor , */,owmay dri11ks do you ,>n.tuml! b, a11a ·u ng e week:*

U @'°None I. ☐ •verugc less chnn I 2. D L- 2 3. ☐ 3-4 4. D 5-6 5. ☐ 7-8

6. D 9-lO 7. ☐ more than 10

14. H,o ma ny limes cnch week do you exercl.!9

I. ☐Les,; chnn I 2. ☐ I•2 3. t:I 3-4 4. ☐ 5-6

5. ☐7-8 6. D 9ormore

15. In gcocn1l 'ftOuld yo u ¥IY y our hc 11h is:

I. CJ Excellenc 2. Ii! VeryGoO<l 3. ☐ Good - D Fair 5.0 Poor

16. Do you us.e"'itanain su91>lcment.s'!

I. D Y,.,, 0. Li:!No 2. Q So mctime,o;

17. Do you usl.' herb.al supplt mt n1s?

I ☐ Y,-s 0. 13"No 2.0 So meti1111"..S

18. Du you u.s4.'11n y o on • ph y sk i.a n prac:'titioocn for your medical *cart'!*

I. ☐ \'t-:-. 0. 11:n\'o 2. ☐ So metimes

£ND- Tlta11k Y"u for your partit'1}Ulliu1r

Menstrual Survey
Symptom Severity Scale !terms and Applicable SF36 Questions
Mar.iball-Blum, LLC

Date: [redacted]

JJ) #: [redacted]

Oirtct ion.s: Please wrlcc- in tbc- appropriate s p1u:t , c>n the scale below, your nufog for the 12symptoms before- t och lime (episode.) that you userh11. oil aod within (l) out hour after using (be oil.

I = No1 Present 2 • S ligh< 3 = Moderate 4 • Severe 5 = Very Severe

1)'mp,om:	Epin,d I		Episodt 2		Episod,J		Epltod;_,4	
I	Pre	Pon	Pre	Post	Pr,	Post	Pre	Post
I Crrunps	4	I	'I		3	I		
' Abdommt1I pain			,					
) Nausea/ VonU1ing								
4 Oi3rnhet 5 H i: :i.dnch								
o Backoche				2				
7. l. g acht'								
8 Genent1ad ung								
lJ 01.llines...:;							I	
10. We..tl..n?s								
: 11, Lx:prcss ,o n								
12 lrr nabilil) "1ood $\\lflgS								

For 1ht following questions, please tell us bow much your menstru al period Uruiu your levelor pflr1icipa1i on in 1h t follo wi ng ac-civhits111 the ii:a m e times as above. Plea u u.st the following scale.

l• No limi1a1ions ?=Minor limilatlQnS 3=SubstantiaJ limitations 4=Severe limita tions
S=Not able to participale io the activity

L1mti uon<ls.t.'<'ndary 1011wns1ru11l dl$('omron:	J:."pisod, I		Episode 2		Episode J		Episode 4	
It, Moderate uc11vi:.:•	Pn	Post	Pre	Post	Pre	Pon	Pr,	Pa_l
17 Sleep	I	I	I	I				
18 ADI ••	2	I	J	I				
19 \\.'o rk!St hool	3	I	<i	i.				

"llfo rl..:r11:l!iJtlJ1+i,1,eJ frw:lud11mo 11/ng a tab,le pu,hl,rg u vo('Ut.tn1d eo.n..:r, bo11t1in!/, o, p»ay,n //<'1lf

•• -IDL -fd11'/lr"t o/ Dm(ll ,l /l lng (n a111plc· eating, bathing,. g(!tting dressed)

Mtnastll Sa1isf11ction Qol-stionairr
Ma,.,,ha l Bl um LLC

Fill1hi, form ouc afler you bt1ve used Mt:nauil for ONE complete eycle.

1. How do you feel about the eflCct ivenessof the product you've heen tllking'!
,•*i:* posi1ivc "f'p<,si1h•e O neut.ml Dnc:gativc .....very negative

2. Would you rixommeod t.h.is produt'l to a friend?
ye:::; no .Ybot ccnain

3. Have you used products for a slmH11r purp<>!>C'?
yes ,loo

Iryes how does1hjs product com)Xl.rc? _ _ _ _ _ _ _ _ _ _ _ _ _ _

4 . Hl) W pleas ant was the fragrance o r odo r of the produ ce?
-vl!'ry p1cas:mt C pk:11$1.tm O neutral □unpleasant ;;.r;_,ery w1pleasan1

5. How a y isit to use the product?
v<.ery easy e.t:>)' ,.< neutral u difficuh Overy difficult

6. Ilow do you feel about the oil applic.a6on of the product?
--1like the o il uppl ic ulion DI doo"t like ii
1t·s OK I ccally don't like i1

If)UU d idn' t like the oilapplicatMln. how would you ch.mgc it?

_____

_____

7. Hove you noticed any unexpected effects from the: p roduct'!

_____

h 1herc un)1hing else you ,i,.oukl like to 1cll us ubout your useol"lhl:i product?

_____

_____

_____

Thank you forcompleting lhis survey.