## Prostate Awareness Foundation Crila® Supplement Evaluation Participant Overview

The Product: Crila® for Prostate is a natural, safe and effective clinically proven, hormone free herbal supplement which helps maintain the health of the prostate gland. Scientists have identified key alkaloids and flavonoids in the proprietary Crinum latifolium species, which naturally support prostate health, help maintain healthy urinary function, and also promote a healthy immune system. Some men have reported not only BPH symptom relief but also a lowering of PSA value.

**Evaluation Goals**: Determine if regular use of Crila® will have a positive impact on reducing the side effects of BPH (Benign Prostatic Hyperplasia) over long term use of six months. (Some men report positive results in less than one month of use.)

Participants: Twenty-five (25) men with BPH of varying degrees of severity. Please see the enclosed BPH questionnaire developed by the American Urological Association (AUA) to determine if you have BPH and how severe.

## Participant Responsibilities:

- 1) Participate in the complete evaluation of six (6) months duration.
- 2) Complete a pre-evaluation questionnaire about yourself and your prostate health to establish a baseline for comparison.
- Participants can remain on any or all pharmaceutical they use currently for their BPH condition.
- 4) Complete a regularly scheduled Weekly/Monthly Progress Diary questionnaire each week for the first three (3) months of the evaluation to monitor your progress. After the first three (3) months, reporting will only be required once per month at the end of each month until the completion of the six (6) month evaluation period.
- 5) After the first three (3) months and again at the end of the six (6) month evaluation participate in a phone interview with Ken Malik to discuss your observations.
- 6) Provide information on the pre-evaluation Personal History Profile about your prostate health including: the date and results of your most recent lab report to include when available: PSA, free PSA, testosterone, C-reactive protein, PCA3, biopsy, MRI, the size of your prostate in grams or cubic centimeters. We realize that not everyone will have this information. But much of this information is usually part of most men's medical history if they have prostate issues and should be updated regularly.
- 7) Lab reports are the financial responsibility of the participant. Most men with prostate problems get these lab tests done regularly, in many cases every three months. Lab reports are not mandatory but very useful!

## Crila Health Responsibilities:

- 1) Provide a six (6) month supply of Crila® for each participant. Depending on recommended individual dose requirements (dosage is by weight) One-Two bottles of Crila®, a 30-day supply, will be given to each participant at the beginning of the evaluation and then replenished at monthly PAF meetings. Participants can also acquire additional product by calling Ken Malik at 415-675-5661 to confirm all Weekly Diary have been received by the PAF. They then can arrange a pickup or shipment.
- 2) Be available to answer any and all questions about Crila® at the start and during the evaluation period. Participants can get information by contacting Sue McKinney at info@crilahealth.com
- 3) Crila Health will strictly adhere to participant confidentiality. It is understood by PAF that Crila Health desires to conduct a 3-month interview with participants who volunteer for share this information, but agreement to an interview is not a condition of participation.

## **Prostate Awareness Foundation Responsibilities:**

- 1) Help in the distribution of product and information at monthly PAF meetings and by phone and email.
- 2) Retrieve the participant pre-evaluation, weekly-monthly diary information and conduct regular phone and email contact with the participant.
- 3) Review, analyze and share the results with participants, Crila Health and PAF membership.
- 4) Participant confidentiality is a priority. At no time will personal information be divulged to any other parties including Crila Health or PAF staff without the express permission of participants. Upon completion of the evaluation process all personal information will be purged from PAF files and databases to further ensure complete privacy.
- 5) At the appropriate time, PAF will pass on Crila Health's invitation to participate in 3 month and 6 month interviews, and connect participants willing to be contacted by Crila Health.



Prostate Awareness Foundation 657 Acacia Lane, Suite # 216, Santa Rosa, CA 95409 415-675-5661 www.ProstateAwarenessFoundation.org

# Prostate Awareness Foundation Crila® Supplement Evaluation DIRECTIONS for PRODUCT USE PARTICIPANT INSTRUCTIONS

#### DAILY:

At the beginning of the Evaluation you will receive 1-2 bottles of Crila® product in a sealed 180 Veggie capsule bottle, which is about a 30-day supply. Because Crila® dosage is weight-determined, some men will need 2 bottles over 30 days. See weight chart below to determine your daily dose. Every 30 days you may acquire more product until the end of the Evaluation. (see below as to how to acquire more product).

You begin with a 90-day Load Phase: When seeking maximum benefit, what is referred to as the Load Phase, the suggested minimum serving on a daily basis is best determined by your body weight. The Load Phase is the period of time you take Crila® in order to achieve maximum benefits. You should divide taking capsules to at least twice a day, preferably during or after meals.

Weight in kilograms:	50-52	52-64	64-78	78-90	90-102	102-115	115-127	127-139	139-152
Weight in pounds:	110-115	115-142	142-172	172-199	199-226	226-253	253-280	280-307	307-334
Number of capsules to	4	5	6	7	8	9	10	11	12
take:									

To maximize the benefits of Crila® it is recommended to wait three (3) hours before consuming any alcoholic beverages.

After 90 days, and if you have achieved your desired result, following the Load Phase, take the Maintenance Phase dose of 2 capsules per day, preferably during or after food.

Please note: At the 90-day point of the Evaluation, if you are unsure whether to end the Load Phase and move into the Maintenance Phase, please consult with Ken or Sue.

Maintenance Phase: It is recommended that to maintain a healthy prostate you take two (2) capsules a day. However, every body is different. You may need to transition to a lower dosage over a period of time if taking 2 capsules per day doesn't seem to be sufficient.

If you experience discomfort while taking Crila®: There are virtually no significant side effects reported when taking Crila®. All natural substances may cause a "side effect" in a small population of sensitive individuals. If you take Crila® on an

empty stomach you may experience mild nausea. If you have a sensitive stomach, it is recommended to take Crila® with a meal. Listen to your body. If you experience mild nausea, you may elect to build up to your Load Phase over a period of days or weeks. "Mild nausea" is defined as nausea that is not severe enough that you need to take any other medicine or product for relief of the nausea. Also, in clinical trials the following was noted: "some mild side effects which do not cause discomfort to patients and are only seen in a small number of patients could occur, such as abdominal distension, dizziness, insomnia."

If you should experience discomfort when taking Crila® and it does not go away with these suggestions, please contact Ken/Sue. You are under no obligation to continue with the survey if you are uncomfortable.

<u>To Acquire More Product:</u> Participants will receive one - two 180 capsule bottles (depending on weight recommended dosage) of Crila® product in several ways:

IMPORTANT: Participants must have completed and mailed all Progress Diaries for the prior Evaluation period. NO additional product will be issued until Progress Diaries are submitted.

- 1. Product will be available at regularly scheduled PAF meetings: see www.prostateawarenessfoundation.org or emails announcing the meetings
- 2. Or call Ken Malik at the Prostate Awareness Foundation @ 415-675-5661 to arrange shipping or pickup at the PAF office in Santa Rosa.

New Test Results? If you have new test results Mid-term or at any time during the Evaluation, please send them to Ken Malik.

<u>ADDITIONAL INFO?</u> At any time during the Evaluation, if you add supplements or medications to your regime, please contact Ken Malik so your Personal History Profile can be updated.

Confidentiality: Please be assured that this form is strictly confidential. The information provided is only for internal tracking and product evaluation purposes. At no time will your personal information be divulged to other parties or revealed to any staff members without your express permission. Upon completion of the study all personal information will be purged from PAF files to insure your complete privacy.



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## Prostate Awareness Foundation Crila® Supplement Evaluation Product and Company Background Frequently Asked Questions (FAQs)

Crila® for Prostate is a natural and effective, safe, clinically-proven, hormone-free herbal supplement which helps maintain the health of the prostate gland. Scientists have identified key alkaloids and flavonoids in this proprietary Crinum latifolium species, which naturally support prostate health, help maintain healthy urinary function, and also promote a healthy immune system.

#### Crila® FAQs:

How many capsules of Crila® for Prostate do I need to take a day?

Crila® for Prostate is a natural herbal remedy that promotes prostate health. Load Phase: When seeking maximum benefit, what is referred to as the Load Phase, the suggested minimum serving on a daily basis is best determined by your body weight. The Load Phase is the period of time you take Crila® in order to achieve maximum benefits. You should divide taking capsules at least twice a day, preferably during or after meals.

To maximize the benefits of Crila® it is recommended to wait three hours before consuming any alcoholic beverages.

Maintenance Phase: It is recommended that to maintain a healthy prostate you take two capsules a day, however every body is different. Listen to your body. You may need to reduce your dosage more gradually to maintain the benefits you have achieved.

See weight-dosage chart on Directions for Product Use/Participant Instructions and on the back of the label on each bottle.

Why is it necessary to take so many capsules? Natural herbal substances are not as concentrated as refined synthetic chemicals. A higher concentration of Crila® for Prostate herb is necessary to actively promote prostate health. In the Load Phase a man needs to take a sufficient amount of Crila® for Prostate as determined by weight to gain the benefits sought.

How many capsules you consume depends on your desired result. If the condition of your prostate does not cause you any problems now, you may take two capsules of Crila® for Prostate capsules daily to support or maintain that healthy condition. If you need active support and are seeking to promote urinary regularity a Load Phase is recommended for at least 60-90 days. To maintain the beneficial effects of Crila® it is recommended that men take a minimum of two capsules of Crila® for Prostate a day in order to maintain a healthy prostate.

When do I take the capsules of Crila® for Prostate for optimal results? Men taking Crila® for Prostate health in the Load Phase, it is recommended you divide usage into two daily servings, preferably during or after meals. Once you have achieved your desired result following the Load Phase, or for the maintenance of an already healthy condition, take 2 capsules per day, preferably during or after food.

When can I expect results? It will take longer for some men than others to achieve the benefit you are seeking. Men taking Crila® for Prostate herb for the first time have reported they begin to feel a beneficial difference within 30-60 days, although many men feel the results sooner. Regardless of how soon you begin to feel the benefits, you should continue the Load Phase during the PAF Evaluation for a minimum of 90 days. After this initial Load Phase, if you have achieved the level of prostate health you desire, you may continue with a Maintenance Phase to maintain the beneficial result.

## How long should I take Crila® for Prostate?

For optimum long-term support, it is recommended that you follow the Load Phase with the recommended Maintenance Phase of a minimum of 2 capsules per day. For men participating in the PAF evaluation, following the Load Phase, you will continue with the Maintenance Phase at a minimum of 2 capsules per day until you've reached a total of 6 months.

Are there any side effects of Crila® for Prostate? There are virtually no significant side effects reported when taking Crila® for Prostate. All natural substances may cause a "side effect" in a small population of sensitive individuals. If you take Crila® for Prostate herb on an empty stomach you may experience mild nausea. "Mild nausea" is defined as nausea that is not severe enough that you need to take any other medicine or product for relief of the nausea. Also, in clinical trials the following was noted: "some mild side effects which do not cause discomfort to patients and are only seen in a small number of patients could occur, such as abdominal distension, dizziness, insomnia."

Can I take Crila® for Prostate if I am currently taking prescription drugs? When taking prescription drugs, it is best to consult with your doctor or healthcare professional concerning taking any other products, including Crila® for Prostate Crila® is a natural dietary supplement designed to promote and support balanced prostate health and therefore should not interfere with most prescription drugs. It is recommended that you wait four hours after taking your normal medication before taking Crila® for Prostate.

Is Crila® for Prostate safe? Crila® for Prostate is a safe, exclusive, effective herbal supplement which supports, promotes and maintains a healthy prostate. Crila® for Prostate health has scientific studies showing beneficial results for men, is approved by Vietnam's Ministry of Health, and has been in use in Vietnam since 2005. Crila® is grown and manufactured under strict organic conditions to ensure consistent quality and purity. Safety and security procedures are followed at every stage, from growing

the plants in fields free of pesticides and chemical fertilizers, to the final processing and packaging - all within the international requirements of Good Manufacturing Practice (GMP) guidelines as issued by the World Health organization (WHO). Our factory is registered with the U.S. FDA. In addition, Crila® has been awarded certification for Good Agriculture and Collection Practice (GACP), Good Laboratory Practice (GLP) and Good Storage Practice (GSP). Prior to being approved by the Ministry of Health for public consumption in 2005, Crila® underwent 15 years of pre-clinical and clinical research; extensive toxicology and pharmacology testing was conducted; and international research in Europe and now in the US, is ongoing. The University of Illinois Chicago, College of Pharmacy has conducted multiple testing over a period of years to confirm Crila® is Estrogen Free. Since approval by the Ministry of Health, thousands of people take Crila® every month, with negligible or no side effects. After Crila® for Prostate herb is processed each batch is tested three times. First, each batch is tested for potency and purity by the World Health Organization certified laboratory in Dr. Tram's factory. A second test is run on each batch by an independent government laboratory under Vietnam's Ministry of Health. And additional testing is conducted by independent American laboratories on behalf of Crila Health before our products are released for consumption.

How was Crila® discovered? Vietnamese pharmacologist, Dr. Nguyen Thi Ngoc Tram, began working with Crinum latifolium L in 1990. The Crinum leaves were a medicinal herb used by generations of Vietnamese traditional doctors. When Crinum was first used, there was so little of the rare wild plants that the substance was reserved for the men and women of the Royal family. Dr. Tram took these rare plants to Europe, where she was invited to conduct her research on promising botanicals used for traditional medicine. When she began researching Crinum latifolium L she discovered although many subspecies of the Crinum latifolium family of plants look the same, only one of the twelve species had the beneficial properties she was seeking. She took that one variety and domesticated the plant on her organic plantations. Over the years she developed a proprietary cultivar from the King's wild Vietnamese Crinum, now recognized as Crinum latifolium L var. crilae Tram & Khanh. Dr. Tram also identified specific molecules in these plants that contain beneficial properties. She developed a process to enhance the extraction of those beneficial alkaloids and flavoniods for manufacture of Crila®. Dr. Tram's plantations are the only source for her clinically tested Crila®. Today's Crila® is a capsule containing this concentrated prostate herb, providing a proprietary extraction which has been formulated to promote and maintain prostate health.

What does Crila® mean? Crila® is Dr. Tram's trademark for her proprietary Crinum latifolium products.

Is Crila® for Prostate made in a modern factory? Dr. Tram's new custom-built factory was dedicated in June 2009. The factory was built using funds provided by men and women from the U.S. and several western countries who had tried Crila® and realized the product could benefit thousands of men and women around the world. The

facility and equipment, processing and laboratory procedures were inspected and approved by Vietnam's Ministry of Health. In addition, the factory has implemented stringent procedures and undergone rigorous inspections to receive GMP (Good Manufacturing Practice) certification according to standards recommended by the World Health Organization, and has been registered with the U.S. FDA. Dr. Tram's factory and plantations have received the following certifications which are the highest international industry standards available: GACP - Good Agricultural and Collection Practice GMP - Good Manufacturing Practice GLP - Good Laboratory Practice GSP - Good Storage Practice

Is the production process safe from contamination? The making of Crila® for Prostate health is a 100% vertically integrated process. All stages of the production, from nurturing the new bulbs, to planting, cultivation and harvest at the plantation, to the extraction and encapsulation processes at the factory, are the responsibility of Dr. Nguyen Thi Ngoc Tram and her family run company. Crinum plant materials are not sourced from other farmers, or harvested from the wild. Dr. Tram believes the other plants do not contain the same balance of biological ingredients as her proprietary cultivar plants. After Crila® for Prostate is processed each batch is tested a minimum of three times. First, each batch is tested for potency and purity by the World Health Organization certified laboratory in Dr. Tram's factory; then a second test is run on each batch by an independent government laboratory under Vietnam's Ministry of Health. A third test is performed for Crila Health by a qualified American laboratory to confirm there has been no adulteration or contamination, and that the products meet Dr. Tram's standards for potency.

Are pesticides or chemicals used for growing the Crinum latifolium plants? No. The soil and water conditions at Dr. Tram's plantations were tested at the Pasteur Institute and the Department of Agriculture before she chose her plantation locations. Her first plantation is located on land that has been used to grow herbal medicines for generations. This land has a history of use for organic farming. Her newest plantation, which was needed to meet the growing international demand for Crila®, is also located in an area strictly reserved for organic farming.

What if Crila® does not work for me? Nothing works for everyone. If you are not satisfied after taking Crila® for Prostate, we will refund your purchase price for up to 100 days from your date of purchase.

Who do I contact for other questions? If you have any questions, please contact our Customer Care department by email at info@crilahealth.com and a representative will respond within 48 hours. You may also call our U.S. toll free number 1-855--CRILA-4U or 1-855-274-5248. If you receive our voicemail, please leave a clear message and an American representative will respond to your call promptly.



## For Immediate Release

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Contact: Ken Malik @ 415-675-5661or kamalik@prostateawarenessfoundation.org

## Prostate Awareness Foundation Evaluating Crila® Supplement to Determine its Efficacy in Men with Benign Prostatic Hyperplasia (BPH)

Santa Rosa, CA. The Prostate Awareness Foundation announced today it will begin recruiting 25 men to participate in an evaluation of Crila®, an herbal supplement made from Crinum latifolium, a prostate herb used by Vietnamese royalty for centuries. The men selected will have different stages of BPH and will be given a six-month supply of Crila® provided by Crila Health.

BPH is the abbreviation for a condition called Benign Prostatic Hyperplasia that affects many men over the age of 40 and the majority of men by 70. BPH does not lead to prostate cancer but many men with prostate cancer also have BPH. Symptoms can include frequent and urgent urination especially at night, the sensation of not completely voiding the bladder, weak urinary stream and the need to urinate again soon after having done so. (See the BPH questionnaire developed by the American Urologic Association to determine your level of BPH)

There are a number of pharmaceutical drugs available for this condition, as well as a multitude of supplements on the market claiming to offer relief for this condition. Surgical intervention in advanced cases can be an option for symptom relief.

Crila® is an herbal supplement derived from a unique strain of *Crinum latifolium*, a lily only grown in Vietnam. Crinum was used by the nobility of Vietnam for centuries to improve prostate health function. All aspects of Crila® are controlled: from research and development, organic cultivation, manufacture and distribution, following industry best practices of "Seed to Shelf." Crila Health has a solid reputation for good business practices and ethics.

Those readers who are experiencing BPH and would like to be considered for this evaluation should contact Ken Malik at the Prostate Awareness Foundation at <a href="mailto:kamalik@prostateawarenessfoundation.org">kamalik@prostateawarenessfoundation.org</a> or call him directly at 415-675-5661. Visit <a href="www.crilahealth.com">www.crilahealth.com</a> for more information about the company and Crila®.

The Prostate Awareness Foundation (PAF) is a not for profit 501(c)(3) based in Northern California. For more information and interviews, please contact:



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