



Growing Herbs for Health

Office of Special Nutritionals,  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration  
200 C St. SW  
Washington DC - 20204

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RECEIVED  
NOV 17 2003  
BY:

October 31, 2003

Aboca USA Inc., located at 126 South Spokane Street/Suite C, Seattle - Washington 98134, submits the following notification of marketing in the United States of an herbal supplement imported from Italy. Aboca will sell the product to medical practitioners and qualified retailers in the USA.

**NOTIFIES**

The marketing of the following Herbal Supplement:

<b>Brand Name:</b>	Bearberry Leaf Herbal Supplement
<b>Presentation:</b>	1.22 Oz (34.7 g) 90 Capsules in glass bottle
<b>Name and address of the manufacturer:</b>	Aboca S.p.a., Via della Liberta' 37/ter - Pistrino di Citema Perugia - Italy
<b>Name and address of the distributor:</b>	Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle Washington - 98134 USA
<b>TEXT OF THE STATEMENT:</b>	<b>Bearberry (Arctostaphylos uva-ursi), also named Uva Ursi, helps maintain a healthy urinary tract.*</b>

**Text of the disclaimer:** \*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

**HERBAL INGREDIENTS (Amount per serving: 2 Capsules):**

Bearberry (leaf) - W.P.C. \*\* 610 mg

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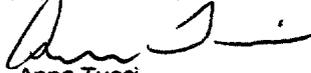
**OTHER INGREDIENTS:** Gelatin (capsule).

86250

**\*\*WPC:** "Whole Phytocomplex Concentrate" (W.P.C.) is a combination of freeze dried extract with the powder of the same portion of the plant.

**WARNING:** Contraindicated in kidney disorders. Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your health care practitioner. Keep out of reach of children.

I Anna Tucci, Executive Vice-President and General Manager of Aboca USA, certify that all the information presented and contained in this notice is complete and accurate, and that Aboca USA has substantiation that the statement is truthful and not misleading.



Anna Tucci

Executive Vice-President  
Aboca USA



**SUGGESTED USE:** Take 2 capsules twice a day or as directed by a qualified health care professional.

**Supplement Facts**

Serving size: 2 capsules  
Servings per container: 45

	Amount Per Serving	% Daily Value
Calories: 2.8		
	mg	%

Bearberry - W.P.C.** ( <i>Arctostaphylos uva-ursi</i> leaf)	610	*
Standardized to 9.54% arbutin, yielding 30 mg per capsule		

Other ingredients: gelatin (capsule).

\* % Daily Value not established

\*\* Whole Phytocomplex Concentrate® (W.P.C.) is a combination of freeze dried extract with the powder of the same portion of the plant.

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**Aboca:  
Growing Herbs for Health**

Since 1978, Aboca has grown herbs using organic farming processes. Today Aboca's farmlands occupy over 1700 acres, all certified organic in accordance with EU Directive 2092/91. Our mission is to provide the safest and most effective herbal supplements, by combining the ancient tradition of herbal remedies with the most sophisticated scientific research and production technology. Aboca is committed, from seed development to final packaging, to making the world's most natural herbal products for health needs, without the use of any chemical excipients or additives.

To learn more about Aboca, visit:  
[www.aboca.us](http://www.aboca.us)  
**MADE IN ITALY**

*The dark glass bottle is temper resistant for your protection, preserving this product from air, moisture and microbial contamination.*

*Outer box prevents any further exposure to the light, fully ensuring its original stability and potency. All materials are completely recyclable. Keep in a dry cool place.*

Herbal Supplement  
**Bearberry**

Leaf



*Arctostaphylos uva-ursi*

**Whole Phytocomplex Concentrate**

Freeze-Dried  
Extract

Micronized Plant  
Powder

305 mg per capsule

Bearberry (*Arctostaphylos uva-ursi*), also named Uva Ursi, helps maintain a healthy urinary tract.\*

This plant is carefully selected by Aboca adhering to the strictest protocols. Systematic quality controls implemented throughout the entire production process and analytical testing performed on raw material and finished product validate the safety and effectiveness of this herbal supplement.

Though arbutin is considered one of the main active ingredients of Bearberry, many other plant components contribute to the herb's efficacy. That is why Aboca has developed the exclusive W.P.C. (Whole Phytocomplex Concentrate) is a combination of the freeze-dried extract with micronized powder from the same portion of the plant, to assure maximum bioavailability, optimum concentration of active principle and the full-spectrum of constituents.

The result is a product with uniform content of arbutin without the use of excipients, colorings, flavorings, or preservatives. GMO free.

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Best before  
Batch No.:



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*Aboca*  
Herbs and Health  
100% Natural

Manufactured by:  
Aboca S.p.A., Via della Liguaria 37ter - Pistoia di Cicogna,  
Parma - Italy  
Distributed by:  
Aboca Usa Inc., 126 South Spokane Street Suite C,  
Seattle - Washington - 98134 USA