



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
 FEB 27 2002

BY: JDS

December 14, 2001

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 a dietary supplement imported from Italy. Aboca will sell the product to medical practitioners, primarily in the Pacific Northwest.

NOTIFIES

The marketing of the following Dietary Supplement:

Brand Name: SEDIVITAX Drops
Presentation: 75 ml (2.54 fl oz)
Name and address of the manufacturer: Aboca S.p.a., Loc. Aboca 20, I-52037 Sansepolcro - ITALY
Name and address of the distributor: Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle Washington 98134

TEXT OF THE STATEMENT: **For relief of occasional sleeplessness or nervous irritability**

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 disease.

DIETARY INGREDIENTS (Amount per Serving - 25 Drops):

- Passionflower - freeze-dried extract (leaf) 33.3 mg;
- Passionflower leaf extract (1:10) in organic grain alcohol 70% (by vol.) 210.2 mg;
- Valerian root extract (1:10) in organic grain alcohol 70% (by vol.) 210.2 mg;
- Lemon balm leaf extract (1:10) in organic grain alcohol 70% (by vol.) 140.1 mg;
- California poppy aerial part extract (1:10) in organic grain alcohol 70% (by vol.) 140.1 mg;

Other ingredients: Essential oil of lavender and marjoram.

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
 Anna Tucci
 Executive Vice-President
 Aboca USA

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Aboca USA, Inc.

SUGGESTED USE

Take 25 drops in a small amount of water twice during the day and 40 drops at night before going to bed. Shake before use.

Supplement Facts

Serving size: 25 drops

Servings per container: 90

	Amount Per Serving	
	mg	% Daily Value
Calories: 388		
Passionflower - Freeze-dried extract ** (Passiflora incarnata L.) (leaf) Standardized to 8% total flavonoids	33.3	*
Passionflower leaf extract ** (1:10) in organic grain alcohol 70% (by vol.) Total flavonoids minimum 0.16%	210.2	*
Valerian root extract (1:10) in organic grain alcohol 70% (by vol.) Total valerenic acids minimum 0.011%	210.2	*
Lemon balm leaf extract ** (1:10) in organic grain alcohol 70% (by vol.) Rosmarinic acid minimum 0.28%	140.1	*
California poppy aerial part extract ** (1:10) in organic grain alcohol 70% (by vol.) Protopine minimum 0.0028%	140.1	*

Other ingredients: essential oil of lavender and marjoram. This product contains no artificial excipients, colorings, flavorings, preservatives. GMO free.

*% Daily Value not established

** Ingredient from organic agriculture

Sedivitax

WARNING:

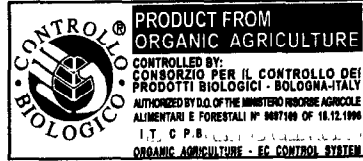
Do not take if you are pregnant or nursing.

For other contraindications and cautions, please consult your health care practitioner.

This product contains organic grain alcohol 70% by volume.

Keep out of reach of children

MADE IN ITALY



DROPS Sedivitax

Herbal Supplement

For relief of occasional sleeplessness or nervous irritability*

Passionflower

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

Net Wt 75 ml (2.54 fl oz)

Aboca
Herbs and Health
100% Natural

Manufactured by:
Aboca s.s., Via della Libertà, 37/ter - Pistrino di Citerna
Perugia - Italy
Distributed by:
Aboca Usa Inc., 128 South Spokane Street/Suite C,
Seattle - Washington - 98134 USA
www.abocausa.com

B

Best before

BATCH n°

Keep in a dry cool place

Batch n°

Best before

SUGGESTED USE

Take 25 drops in a small amount of water twice during the day and 40 drops at night before going to bed. Shake before use.

Net Wt 75 ml (2.54 fl oz)

Sedivitax

DROPS

Each 75 ml (86.4 g) bottle contains:
passionflower freeze-dried extract 3 g.
Extracts (1:10) in organic grain alcohol 70% (by volume) of:
passionflower (leaf) 18.9 g,
valerian (root) 18.9 g, lemon balm (leaf) 12.62 g, California poppy (aerial part) 12.62 g,
essential oil of lavender 0.17 g and marjoram 0.19 g.

Distributed by: Aboca Usa Inc., 128 South Spokane Street/Suite C, Seattle - Washington 98134 USA www.abocausa.com

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