

LABORATEC technology and health - Data sheet

PRODUCT ESPECIFICATIONS LABORATEC		PRODUCT CODE: DS Contrurine Plus.	
NAME:	CONTRURINE PLUS. 30 cápsulas	Date:	07/09/2013
Brand:	Laboratec	Pages:	8

PRODUCT TRADENAME

CONTRURINE PLUS. 30 vegetable capsules.

PRODUCT DESCRIPTION

Food Supplements elaborate from GABA, plants, fish oil rich in omega 3, rutin and vitamin B₆

Product in capsules, manufactured by homogeneous mixing of ingredients.

Presentation packs of 30 capsules. **Net content: 11 g.** It Contains 30 capsules of 370 mg.

The plant extracts used in the preparation of this food supplement are guaranteed and are conformity in the relevant certificates, with:

- KONINKLIJK BESLUIT van 29 AUGUSTUS 1997 betreffende de fabricage van en de handel in voedingsmiddelen die uit planten of uit plantenbereidingen samengesteld zijn of deze bevatten (B.S. 21.XI.1997).
 - RÉPUBLIQUE FRANÇAISE: Arrêté du 24 juin 2014 établissant la liste des plantes, autres que les champignons, autorisées dans les compléments alimentaires et les conditions de leur emploi NOR : *ERNC1406332A*.
 - MINISTERO DELLA SALUTE: DECRETO 9 luglio 2012. Disciplina dell'impiego negli integratori alimentari di sostanze e preparati vegetali (G.U. 21-7-2012 serie generale n. 169).
 - GERMANY: Government and Federal State Authorities List of Substances of the Competent Federal Government and Federal State Authorities Category "Plants and plant parts".
 - ENGLAND: List of plants used for feeding.
 - SPAIN: Royal decree 1487/2009, of 26 September concerning food supplements. + AFEPADI Proposed modification to include plants and other than vitamins and minerals. January 10, 2013.
 - Committee: Novel Food Catalogue.
 - List of plants PROJECT "BELFRIT".
- Other ingredients used in the elaborate of this food supplement are consistent with existing legislation based on:
- Food supplements.
 - Proposals AESAN and AFEPADI to extension of the Royal Decree of Food supplement.
 - COMMITTEE: New food or food ingredients authorized for use in food supplement.
 - Other countries in the EU.

NAME OF SALE:

FOOD SUPPLEMENTS

Elaborated on the basis of GABA, plants, fish oil rich in omega 3, rutin and vitamins

FORMAT:

Capsules (Blister of 15 capsules).
30 capsules of 370 mg per capsule.

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INGREDIENTS:

Ingredients per capsule:

GABA (gamma amino butyric acid) (70 mg), dried grape seed extract (*Vitis vinifera* L, seeds) (45 mg), maltodextrin (freight), microencapsulated fish oil (30 mg, eq. 11, 7 mg of fish oil), Rutin (25 mg), anti-caking agents (silicon dioxide, magnesium stearate), pyridoxine hydrochloride (1.86 mg, eq. to 1.5 mg of Vitamin B6).

Components of the coverage of the capsule: Vegetable.

LIST OF INGREDIENTS (High to Low)

Substance	Scientific Name	Part Used	Galenic form	Amount per Take	Ingredients
GABA	Gamma Amino Butyric Acid	--	Powder	70 mg	Active principle
Grapeseed	<i>Vitis vinifera</i> L	Seeds	Dried extract	45 mg	Active principle
Freight agents	Maltodextrin	--	Powder	c.p.s.	Freight agents
Microencapsulated Fish oil	Starch, fish oil, water and antioxidant.	Fish oil	Oil microencapsulated	30 mg	Excipient
Rutin	Rutin	--	Powder	25 mg	Active principle
Caking	Silicon dioxide	--	Powder	c.p.s.	Excipient
Vitamin B6	Magnesium stearate	--	Powder	1.86 mg	Co-factor of enzymatic reactions

INGREDIENTS LIST OF COVER CAPSULE

Components	Amount per capsule
Vegetable	100 mg

DAILY AMOUNTS of nutrients and ingredients

Nutrient and ingredients	Amount per day (1 capsule)	% NRV*
GABA	70 mg	--
Grapeseed	45 mg	--
• Proanthocyanidins (95%)	42,8 mg	--
Fish oil	11,7 mg	--
• EPA (18%)	2,1 mg	--
• DHA (12%)	1,4 mg	--
Rutin	25 mg	--
• Rutin (96.4%)	24,1 mg	--
• Quercetin (3.6%)	0,9 mg	--
Vitamin B6 (pyridoxine)	1,5 mg	107,2%

* **NRV: Nutrient Reference Value.**

NRV: Nutrient Reference Value. Under Regulation 1169/2011 of the European Parliament and the Council of October 25, 2011 on food information to consumers

NUTRITIONAL INFORMATION ON PRODUCT

Nutriente	Galenic form	Amount per take 1 capsule per day	% NRV
Vitamin B6	Pyridoxine hydrochloride	1.5 mg	107,2%

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Vitamins and Minerals	NRV ¹	Threshold value in CA -Italia	Threshold value in CA -Benelux	Threshold value in CA -France ²	UL (Maximum Intake Tolerable)	Proposal MSL (Maximum Supplement Levels)
Vitamin B6 (mg)	1,4	6	6	2	25	18-93

¹ Nutrient Reference Values under Regulation 1169/2011
² Arrêté Français du 9 mai 2006 relatif aux nutriments pouvant être employés dans la fabrication des compléments alimentaires
³ Ceilings canceled by the State Council: Decision n° 295235 27/04/2011.
 QS = Quantum satis.
 Folic acid: Reg 1135/2014. Authorization claims Art.14 (Supplementation of 400 mcg of folic acid).

INFORMATION ON THE PLANT SPECIES PRODUCT

Common Name	Botanical Name	Used Part	Dosage Form	Plant ratio / extract	Daily take amount 1 capsule
Grape seeds	Vitis vinifera L	Grape seeds	Dried extract	--	45 mg

Kind Vegetable	Active Substance (%)	Daily take amount (1 capsule)
Vitis vinifera L (Vid)	Proanthocyanidin (95%)	42,8 mg

MEDICINAL PLANTS:

The plant extracts used in the elaboration of this food supplements are guaranteed and are in line with legislation in other EC countries that have legislation in this regard:

SCIENTIFIC NAME	COMMON NAME	AUTHORIZED PART	STANDARDIZATION OF ACTIVE PRINCIPLE	LIMITS or WARNINGS
<i>Vitis vinifera L</i>	Vine	Grape seed. Belgium and Italy: fruit, leaf, and seed. Belgium and France: fruit, leaf, leaf buds and seeds. Germany: Sheet (list B). England: leaves.	Proanthocyanidins in different countries does not refer to any specific one. Belgium: Proanthocyanidins. Stilbenes: for example, resveratrol, viniferinas. Fruit acids. Flavonoids (4%-5%): for example, kaempferol, quercetin	No reference. Germany: • ESCOP: 10 g / 250 ml water.

INFORMATION ON OTHER INGREDIENTS

Other substances	Galenic Formula	Daily take amount (1 capsule)
GABA (Gamma Amino Butyric Acid)	Powder	70 mg
Fish Oil	Fish oil microencapsulated (39%)	11,7 mg
Rutin	Powder	25 mg

Substance	Active Substance (%)	Daily take amount (1 capsule)
Fish oil	EPA (18%) DHA (12%)	2,1 mg 1,4 mg
Rutin	Rutin (96,4%) Quercetin (3,6%)	24,1 mg 0,9 mg

Draft Royal Decree amending Royal Decree 1487/2009, of 26 September concerning food supplements is modified.

COMMISSION: New food or food ingredients authorized for use in food supplements.

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OTHER SUBSTANCES WITH NUTRITIONAL OR PHYSIOLOGICAL EFFECT THAT MIGHT BE USED IN THE MANUFACTURE OF FOOD SUPPLEMENTS

CHART AESAN – AFEPAI (2013)

Group	Substance	Maximum Daily Quantities AESAN	Maximum Daily Quantities AFEPAI	Warnings Proposed Scientific Committee
FATTY ACIDS	OMEGA 3: DHA + EPA	3 g	3 g	
CAROTENOIDS AND FLAVONOIDS	RUTIN	150 mg (Si Rutin + Quercetin, máx. 75 mg de quercetin)	600 mg (If Rutin + Quercetin, máx. 300 mg of quercetin)	At these doses: Not recommended for pregnant women.

OTHER COUNTRIES:

ESPAÑA:

EPA y DHA:

- AESAN has proposed a maximum daily amount for the amount of docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) of 3 g. This proposal is based on EFSA scientific opinion stating that intakes of DHA and EPA supplements combined at doses up to 5 g does not raise safety (EFSA 2012).
- In Belgium and Italy (legislative proposal) are authorized in food supplements without a maximum daily quantity (Belgium, 1992) (Italy, 2012) have been established.
- In Denmark are also allowed. In the case of DHA, the maximum total amount used must not exceed 1,050 mg per recommended daily dose in the case of the EPA, the maximum total amount used must not exceed 1,500 mg per recommended daily (Denmark, 2011) dose.

RUTIN.

- AESAN has proposed a maximum daily amount of 150 mg rutin with the warning "not recommended for pregnant women." This proposal is based on the existence of a favourable assessment in France whereas 150 mg / day rutin provide 75 mg / day of quercetin (AFSSA, 2008).

ITALY:

INDICE DEGLI INTEGRATORI NUTRIZIONALI

L'Indice elenca i nutrienti secondo la nomenclatura più frequente utilizzata in letteratura. I nomi in grassetto (maiuscolo) sono i titoli delle Monografie. per i nomi alternativi o i sinonimi, sono citate le Monografie di riferimento.

ACIDI NUCLEICI / NUCLEOTIDI

- Acidi omega 3 (Cfr Acido docosaesaenoico (DHA))
- Acidi omega 3 (Cfr Acido eicosapentaenoico (EPA))
- Acidi omega 3 (Cfr Olio di pesce).

RUTIN.

BELGIUM:

GABA: It is considered among the substances no novel food in food supplements.

EPA y DHA: It is considered among the substances no novel food in food supplements.

RUTIN: It is considered among the substances no novel food in food supplements.

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NUTRITION OR HEALTH ALLEGATIONS

INTERNATIONAL PATENT:

- Contributes to the welfare of the urinary tract.

Some of the ingredients used for making the product have any claim authorized time.

NUTRITION CLAIMS APPROVED AND CONDITIONS OF USE SET OUT IN THE ANNEX TO REGULATION CE Nº1924 / 2006 and EC Regulation No. REGULATION (EU) No 432/2012 OF THE COMMISSION of May 16, 2012.

- Charts declarations authorized by this regulation.
- Recitals:
 - **(10)** The Commission has found that the Authority has not yet completed the scientific assessment of a number of statements under evaluation relate to the effects of certain plant or herbal substances, commonly known as "botanical" substances. In addition, a number of health claims for which the Commission or demand a more thorough assessment before considering joining the list of permitted claims or cannot decide on its inclusion on the list, although they have been evaluated due to other legitimate factors.
 - **(11):** Statements whose evaluation by the Authority or whose consideration by the Commission has not finished yet published on the website of the Commission (1) and can still be used, in accordance with Article 28, paragraphs 5 and 6 of Regulation (EC) nº1924 / 2006.

HEALTH CLAIMS:

- Vitamin B6: Supports normal nervous system function and normal psychological function.

DECLARATION	CONDICIONES O RESTRICCIONES DE UTILIZACIÓN DEL ALIMENTO, DECLARACION COMPLEMENTARIA O ADVERTENCIA
Vitamin B6	Vitamin B6 contributes to the normal functioning of the nervous system. This statement can be used only for food which is at least a source of vitamin B6 in accordance with the SOURCE OF [NAME OF VITAMIN] statement AND / OR [NAME OF MINERAL] as listed in the Annex to Regulation (EC) No 1924/2006.
	Vitamin B6 contributes to normal physiological function. This statement can be used only for food which is at least a source of vitamin B6 in accordance with the SOURCE OF [NAME OF VITAMIN] statement AND / OR [NAME OF MINERAL] as listed in the Annex to Regulation (EC) No 1924/2006.

AVERAGES AND TOLERANCES OF NUTRIENTS FORMULA (Vitamins y minerales)

AVERAGES AND TOLERANCES				per 10 ml	Tolerances		
Vitamins and/or Minerals		NRV	15% NRV	Labelled amount	Lower limit	Maximum limit	NRV (%)
Vitamin B6	mg	1,4	0,21	1,5	1,2	2,3107.2	107,2 %

NUTRITIONAL INFORMATION

In food supplements are not obligatory to include nutritional information on the label.

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INFORMATION ABOUT ALLERGENS

As set out in Directive 2000/13 / EC, 2003/89 / EC, 2006/142 / EC and 2007/68 / EC this product does not contain allergens.

INFORMATION ABOUT GMOs

This product does not contain raw materials derived from genetically modified organisms, as this-defined by Directive 2001/18 / EC as amended. According to Regulation (EC) No. 1829/2003 and No. 1830/2003 this product is not subject to additional labelling requirement.

RECOMMENDED DOSE

Take 1 capsule per day (at night) with a glass of water.

HOW TO USE

Take 1 capsule with a glass of water at night.

BEFORE DATE

3 years from date of manufacture.

OBSERVATIONS

Do not exceed the stated recommended daily dose.
Food supplements should not be used as a substitute for a varied and balanced diet and a healthy lifestyle.
Keep out of reach of young children.
It is advisable to follow a healthy lifestyle.

CONSUMER WARNINGS

AESAN does not recommend the use of Rutin in pregnant women when the doses are 150 mg / day (Rutin + Quercetin (maximum 75 mg)).

CONSUMER ADVICE

None

CONSUMER POPULATION

Adolescents and Adults

STORAGE CONDITIONS:

Keep the product in a cool, and dry environment away from direct light.

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PRODUCT LABELLING

CONTRURINE PLUS 30 Capsules

FOOD SUPPLEMENTS Net Content:

Welfare of the urinary tract.

FOOD SUPPLEMENTS

Made from GABA, plants, fish oil rich in omega 3, rutin and vitamins

Ingredients per capsule:

GABA (gamma-amino-butyric acid) (70 mg), Grape Seed Extract (*Vitis vinifera* L., grapes) (45 mg), Maltodextrin (freight agents), Fish oil microencapsulated (30 mg, eq a 11,7 mg de fish oil), Rutin (25 mg), Anticaking (silicon dioxide, magnesium stearate), pyridoxine hydrochloride (1.86 mg, eq. to 1.5 mg of Vitamin B6).

Components of the coverage of the capsule: Vegetable, water and food colouring (titanium dioxide)

Nutrient and ingredients	Quantity per day (1 capsule)	% NRV*
GABA	70 mg	--
Grape seed	45 mg	--
• Proanthocyanidins (95%)	42,8 mg	--
Fish oil	11,7 mg	--
• EPA (18%)	2,1 mg	--
• DHA (12%)	1,4 mg	--
Rutin	25 mg	--
• Rutin (96.4%)	24,1 mg	--
• Quercetin (3.6%)	0,9 mg	--
Vitamin B6 (pyridoxine)	1,5 mg	107,2%

* NRV: Nutrient Reference Value.

How to use / Recommended daily intake:

Take one capsule per day with a glass of water (at night).
Do not exceed the stated recommended daily dose.
Food complements should not to be use as a substitute for a varied and balanced.
Keep out of research of children
It is important to follow a healthy lifestyle.

Net Content:

9 g. Content 30 capsules of 370 mg.

Special storage conditions:

Cool and dry place, away from direct light

Lot and consume preferably before the end of (month/year): (see packaging).

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PRODUCT STABILITY AND SAFETY INFORMATION

PRODUCT SAFETY INFORMATION

To evaluate the safety of the products, they have been taken into account several factors:

- The regulation for this product.
- Characteristics of each ingredient, toxicological profiles.
- No unauthorized ingredient.
- Quantitative and qualitative. Doses of nutrients to match the security.
- Compatibility of the ingredients of the formulation.
- Microbial conditions.
- Possible sources identify allergens.
- Cite documentation.

Based on assessment of the safety of products, declare that its use is safe and appropriate, taking into account the warnings mentioned in their labelling. It does not exist any known toxicity to the RDA.

PRODUCT STABILITY INFORMATION

Based on stability studies conducted at the above product:

- Its organoleptic properties.
- The physical-chemical properties.
- Microbiological properties.

Declare that under normal storage and use conditions of the said product, the product maintains its characteristics during the period from manufacture to the best before date specified on the packaging.

MECHANISM OF ACTION

GABA is an inhibitory neurotransmitter of the central nervous system responsible for the muscle tone. It controls the hormone responsible of the re-absorption of water molecules by urine concentration and volume reduction.

Extracts from grape seeds - proanthocyanidins OPC (condensed tannins) are a class of polyphenols found in a variety of plants. OPC focuses on stabilizing vascular tissue structures (elastic) and connective, regulate blood flow towards the lower extremities and has an anti-inflammatory, antibacterial and astringent role.

Rutin are a class of flavonoids that are antioxidant, anti-inflammatory and strengthens capillaries having antidiuretic and vasodilating properties which influence the urinary voiding



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