

TECHNICAL DATA SHEET

LACTOBIOME

Code

4003120 Lactobiome sale 10 ml Bormioli 3f

Client

Crosspharma

Category

Food supplement

subcategory Reg. (CE) n. 1333/2008 and following edits Reg. (UE) 1129/2011

17.2 Food supplements supplied in a liquid form

Description

Food supplement with probiotics, galactooligosaccharides, vitamin B1, B2, B3 and B6.

Packaging

Sales: 10 PET amber vials (2003174) with Bormioli 3F cap

Sales box (mm) 128 X 70,5 X 51,5 5 colours, water varnish. Label(mm) 40 X 26, 5 colours UV varnish. Foglietto (mm) 150 x 160, 1 colour
24 boxes per carton.

Net quantity

Sale: 10 ml e

Ingredients

CAP: *Saccharomyces boulardii* (CNCM-1-3799); bulking agent: maltodextrins, microcrystalline cellulose; probiotic mix: *Bifidobacterium bifidum* HA-132 (BCCM/LMG ID11719), *Lactobacillus delbrueckii ssp. bulgaricus* HA-137 (BCCM/LMG ID10482), *Lactobacillus acidophilus* HA-122 (BCCM/LMG ID11722), *Streptococcus thermophilus* HA-110 (BCCM/LMG ID10476) (contains **milk** and **soy**); *Lactobacillus rhamnosus* GG (ATCC 53103); Anti-caking agent: magnesium salts of fatty acids, silicon dioxide; nicotinamide; riboflavin 5'-phosphate, sodium; pyridoxine hydrochloride; thiamin hydrochloride.

VIAL : Purified water; galacto-oligosaccharides (contains **milk**); fructose; preservatives: sodium benzoate, potassium sorbate; flavour; acid: citric acid.

Nutritional information		Per 1 vial (10 ml)	Per 100 ml	%NVRs*
Vitamin B1	mg	0.44	4.4	40%
Vitamin B2	mg	0.56	5.6	40%
Vitamin B3	mg	6.4	64	40%
Vitamin B6	mg	0.56	5.6	40%
Galacto-oligosaccharides	g	1	10	
<i>Saccharomyces boulardii</i>	CFU	1X10 ⁹	10X10 ⁹	
<i>Lactobacillus rhamnosus</i>	CFU	3X10 ⁹	30X10 ⁹	
<i>probiotic mix: Bifidobacterium bifidum, Lactobacillus delbrueckii ssp. bulgaricus, Lactobacillus acidophilus, Streptococcus thermophilus</i>	CFU	1X10 ⁹	10X10 ⁹	

* NRVs= Nutrient Reference Values

Recommended daily dose

1-2 Vials at day

Allowed claims in EU (Reg.432/2012)

Claim type: art. 13.1 reg. 1924/2006 (general function health claims)

Vitamin B1 contributes to:

- normal energy-yielding metabolism
- normal functioning of the nervous system
- normal psychological function
- the normal function of the heart

Vitamin B2 contributes to:

- normal energy-yielding metabolism
- normal functioning of the nervous system
- the maintenance of normal mucous membranes
- the maintenance of normal red blood cells
- the maintenance of normal skin
- the maintenance of normal vision
- the normal metabolism of iron
- the protection of cells from oxidative stress
- the reduction of tiredness and fatigue

Vitamin B3 contributes to:

- normal energy-yielding metabolism
- normal functioning of the nervous system
- normal psychological function
- the maintenance of normal mucous membranes
- the maintenance of normal skin
- the reduction of tiredness and fatigue

Vitamin B6 contributes to:

- normal cysteine synthesis
- normal energy-yielding metabolism
- normal functioning of the nervous system
- normal homocysteine metabolism
- normal protein and glycogen metabolism
- normal psychological function
- normal red blood cell formation
- normal function of the immune system
- the reduction of tiredness and fatigue
- the regulation of hormonal activity

Note

Any information other than compulsory ones is provided on a voluntary basis at the discretion of the operator that sells the product under its own name, in accordance with current legislation, with particular regard to the provisions of Reg. (EU) No. 1169/2011 and Reg. (EC) n. 1924/2006, as amended. The graphical control by Inpharma will cover only the data within its competence in this document.

Regulations

- Regulation (UE) n. 1169/2011
- Directive 2002/46
- Regulation (CE) n.178/2002
- Regulation (CE) n.1170/2009
- Regulation (CE) n.2073/2005
- Regulation (CE) n.396/2005
- Regulation (CE) n.2015/2283
- Regulation (CE) n.852/2004
- Regulation (CE) n.1924/2006
- Regulation (CE) n.1333/2008
- Regulation (CE) n.432/2012
- Regulation (CE) n.1881/2006
- Regulation (CE) n.1334 2008
- Directive 2009/32/CE

Warnings

Keep out of the reach of children under three years.

Don't exceed the recommended dose. Food supplements are not intended as a substitute for a varied and balanced diet and a healthy lifestyle. The content in probiotics refers to the product properly stored.

Shelf life

24 months

Storage conditions

Store in a cool, dry place, at room temperature, below 25°C, away from light and heat sources. The expiry date refers to the product properly stored in unopened package.

Specifications

Organoleptic characteristics

Solution Test	Method	Acceptance criteria
Appearance	organoleptic	Clear solution
Colour	organoleptic	colourless
Odour	olfactory	Characteristic
Powder Test	Method	Acceptance criteria
Appearance	organoleptic	Fine powder
Colour	organoleptic	Beige, dark dots
Odour	olfactory	Characteristic

Physical/chemical characteristics

Solution test	Method	Units	Acceptance criteria
Content sale	gravimetric	ml	9.5 – 11.4
Density	gravimetric	g/ml	1.06 – 1.16
pH	potentiometric		3.9 – 4.9
Powder test	Method	Units	Acceptance criteria
Humidity	Internal method	%	≤ 4.00

Vitamin B1	HPLC	mg/g	1.97 - 3.7
Vitamin B2	HPLC	mg/g	2.5 - 4.7
Vitamin B3	HPLC	mg/g	28.7 - 53.8
Vitamin B6	HPLC	mg/g	2.5 - 4.7

Microbiological characteristics

Powder test	Method	Units	Acceptance criteria
Total aerobic bacteria	Iso 4833-1:2013	cfu/g	≤ 10,000
Yeast and moulds	Iso 21527-2	cfu/g	≤ 100
E.coli	ISO 9308:1		Negative/g
Enterobacteriaceae	ISO 21528-1	cfu/g	≤ 100
Salmonella	ISO 6579-1	cfu/g	Negative/10g
S. aureus	ISO 6881-3	cfu/g	Negative/g
Total probiotics	Internal	cfu/g	28X10 ⁹

Gluten and lactose

Test	Method	Acceptance criteria
Gluten	Internal	Negative

Allergens

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES [REGULATION (EU) NO. 1169/2011]	PRESENCE	ABSENCE
Cereals containing gluten , namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof.		X
Crustaceans and products thereof.		X
Eggs and products thereof.		X
Fish and products thereof.		X
Peanuts and products thereof.		X
Soybeans and products thereof.	X	
Milk and products thereof (including lactose).	X	

Nuts , namely: almonds (<i>Amygdalus communis</i> L.), hazelnuts (<i>Corylus avellana</i>), walnuts (<i>Juglans regia</i>), cashews (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nuts (<i>Bertholletia excelsa</i>), pistachio nuts (<i>Pistacia vera</i>), macadamia or Queensland nuts (<i>Macadamia ternifolia</i>), and products thereof.		X
Celery and products thereof.		X
Mustard and products thereof.		X
Sesame seeds and products thereof.		X
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO ₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.		X
Lupin and products thereof.		X
Molluscs and products thereof.		X

GMO, BSE, TSE STATEMENT	PRESENCE	ABSENCE
The product are not, do not contain and are not produced from genetically modified organisms (GMO)		X
The product can be considered Transmissible Spongiform Encephalopathy (TSE) free		X
The product can be considered Bovine Spongiform Encephalopathy (BSE) free		X

Date and signature for acceptance

06/11/2020
REV.01