

## Product Specification

### 1. Master data

Client	Internal		
Product	Orthofortin B-Komplex		
Article number	4270000073526		
EAN-Code PZN	4270000073526 15329906		
Dosage form	Tablet (30)	Shelf life	36 months
Weight per unit	450 mg	Measurements	10 mm

### 2. List of ingredients

List of Ingredients in descending order, active ingredients quantitatively

No.	Ingredient	A=active I=inactive	Amount of active agent	Unit	Active ingredient	Category of additive
1	Microcrystalline cellulose	I	(280)	(mg)		Bulking Agent
2	Potato starch	I	(81,39)	(mg)		Bulking Agent
3	Pantothenic acid	A	25	mg	Vitamin B5	
4	Niacin	A	15	mg	Vitamin B3	
5	Thiaminnitrat	A	15	mg	Vitamin B1	
6	Riboflavin	A	15	mg	Vitamin B2	
7	Pyridoxinhydrochlorid	A	10	mg	Vitamin B6	
8	Magnesium stearate	I	(4)	(mg)		Anticaking agent
9	Silicon dioxide	I	(4)	(mg)		Humectant agent
10	Folic Acid	A	450	µg		
11	Biotine	A	150	µg	Vitamin H	
12	Cyanocobalamin	A	10	µg	Vitamin B12	

Microcrystalline cellulose (BA), Potato Starch (BA), Pantothenic acid, Niacine, Thiamin hydrochloride, Riboflavin, Pyridoxine hydrochloride, Magnesium salts of fatty acids (ACA), Silicon dioxide (ACA), Folic Acid, Biotine, Cyanocobalamin  
(BA = Bulking agent, ACA = anti caking agent)

Mikrokristalline Zellulose (FS), Kartoffelstärke (FS), Pantothensäure, Niacin, Thiaminhydrochlorid, Riboflavin, Pyridoxinhydrochloride, Magnesiumstearat (TM), Siliziumdioxid (TM), Folsäure, Biotin, Cyanocobalamin  
(FS = Füllstoff, TM = Trennmittel)

### 3. Allergens and food intolerances

The product contains substances causing allergies or intolerances according to Annex II of Regulation (EU) No. 1169/2011.

X	NO	Contains	
<input type="checkbox"/>	YES	Ingredient	Cereals containing gluten, namely: wheat (such as spelt and Khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof (Comment: Contains mannitol derived from wheat and/or maize).
<input type="checkbox"/>			Crustaceans and products thereof
<input type="checkbox"/>			Eggs and products thereof
<input type="checkbox"/>			Fish and products thereof
<input type="checkbox"/>			Peanuts and products thereof
<input type="checkbox"/>			Soybeans and products thereof
<input type="checkbox"/>			Milk and products thereof (including lactose)
<input type="checkbox"/>			Nuts (i.e. almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut) and products thereof
<input type="checkbox"/>			Celery and products thereof
<input type="checkbox"/>			Mustard and products thereof
<input type="checkbox"/>			Sesame seeds and products thereof
<input type="checkbox"/>			Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of total SO <sub>2</sub>
<input type="checkbox"/>			Lupin and products thereof
<input type="checkbox"/>			Mollusc and products thereof

\*Exempt from allergen labelling according to Annex II of Regulation (E) No 1169/2011

#### **Genetic engineering:**

For the above mentioned product there is no obligation of g.m.o. labelling as defined by the Regulations (EC) No 1829/2003 and 1830/2003 of the European Parliament and the Council of 22<sup>nd</sup> September 2003.

#### 4. Further details

##### 4.1 Nutritional information

Nutrient content	Per 100 g		Per Unit (450 mg)	
Energy	1357	KJ	6,137	KJ
	319	Kcal	1,444	Kcal
Fat	0	g	0	g
- saturated	0	g	0	g
Carbohydrates	79,86	g	0,361	g
- sugars	0	g	0	g
Protein	0	g	0	g
Salt	0	g	0	g

Nutrient	unit	Per serving 1 Tablet	In 100 g	%RI / tablet
Pantothenic acid	mg	25	5,907	445
Vitamin B3	mg	15	3,31	93,75
Vitamin B1	mg	12,15	2,69	1105
Vitamin B2	mg	15	3,31	1071
Vitamin B6	mg	10	2,212	714
Folic Acid	µg	450	0,099	225
Vitamin H	µg	150	0,0331	300
Vitamin B12	µg	10	0,0026	47

\*DAILY REFERENCE INTAKES according to the Regulation (EU) No 1169/2011 of the European Parliament

## 4.2 Other

### Description:

Declared unit                      Tablet

### Sensory test of Tablet

Form	round
Surface	almost smooth
Colour	yellow
Odour	characteristic
Taste	characteristic

### Microbiology:

Total viable aerobic count	$\leq 1\,000$ cfu/g
Yeast/Mould	$\leq 100$ cfu/g
Escherichia coli	not detectable in 1 g
Salmonella	not detectable in 25 g

Typical analysis based on random sampling. (cfu = colony forming units)

Created/amended on:	30.10.2018	by:	Dr. A. Lemke
Released by client:	Dr. A. Lemke		