

Product Specification

1. Master data

Client	Internal		
Product	Orthofortin Zimacal		
Article number	4270000073519		
EAN-Code PZN	4270000073519 15330878		
Dosage form	Tablet (30)	Shelf life	36 months
Weight per unit	650	Measurements	12 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	Calcium carbonate	A	350	mg	Calcium	
2	Magnesium citrate	A	150	mg	Magnesium	
3	Microcrystalline Cellulose	I	(120)	(mg)		Bulking Agent
4	Potato starch	I	(14,966)	(mg)		Bulking Agent
5	Zinc gluconate	A	5	mg	Zinc	
6	Magnesium stearate	I	(5)	(mg)		Anticaking Agent
7	Silicon dioxide	I	(5)	(mg)		Humectant Agent
8	Cholecalciferol	A	30	µg	Vitamin D	
9	Menaquinone	A	4	µg	Vitamin K	

Calcium carbonate, Magnesium citrate, Microcrystalline cellulose (BA), Potato Starch (BA), Zinc gluconate, Magnesium salts of fatty acids (ACA), Silicon dioxide (ACA), Zinc gluconate, Cholecalciferol, Menaquinone
(BA = Bulking agent, ACA = anti caking agent)

Calciumcarbonat, Magnesiumcitrat, Mikrokristalline Zellulose (FS), Kartoffelstärke (FS), Zinkglucoant, Magnesiumstearat (TM), Siliziumdioxid (TM), Chloecalciferol, Menaquinone
(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 ₂
<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 abovementioned 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 22nd September 2003.

4. Further details

4.1 Nutritional information

Nutrient content	Per 100 g		Per Serving (650 mg)	
Energy	353	KJ	2,3	KJ
	83,1	Kcal	0,54	Kcal
Fat	0	g	0	g
- saturated	0	g	0	g
Carbohydrates	20,77	g	0,135	g
- sugars	0	g	0	g
Protein	0	g	0	g
Salt	0	g	0	g

Nutrient	unit	Per serving 650 mg	In 100 g	%RI / tablet
Calcium	mg	142	21,94	18
Magnesium	mg	8,08	1,24	2,15
Zinc	mg	0,72	0,11	7,17
Vitamin D3	µg	40	0,00062	80
Vitamin K2	µg	0,03	0,0046	40

*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	brownish yellow
Odour	characteristic
Taste	characteristic

Microbiology:

Total viable aerobic count	$\leq 1\,000$ cfu/g
Yeast/Mould	≤ 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		