

# **Product Specification**

#### 1. Master data

Client	Internal			
Product	Orthofortin Vitamin D 5600			
Article number	4270000073564			
EAN-Code PZN	4270000073564 15330861			
Dosage form	Tablet (60)	Shelf life	36 months	
Weight per unit	120 mg	Measurements	6 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		(109,6)	(mg)		Bulking Agent
2	2 Potato Starch		(8,24)	(mg)		Bulking Agent
3	3 Magnesium stearate		(1)	(mg)		Anticaking Agent
4	Silicon dioxide	I	(1)	(mg)		Humectent Agent
5	Cholecalciferol	Α	140	μg	Vitamin D3	
6						
7						
8						
9						
10						
11						
12						
13						

Microcrystalline cellulose (BA), Potato Starch (BA), Magnesium salts of fatty acids (ACA), Silicon dioxide (ACA), Cholecalciferol (BA = Bulking agent, ACA = anti caking agent)

Mikrokristalline Zellulose (FS), Kartoffelstärke (FS), Magnesiumstearat (TM), Siliziumdioxid (TM), Chloecalciferol (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.

Χ	NO	Contains	
	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).
			Crustaceans and products thereof
			Eggs and products thereof
			Fish and products thereof
			Peanuts and products thereof
			Soybeans and products thereof
			Milk and products thereof (including lactose)
			Nuts (i.e. almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut) and products thereof
			Celery and products thereof
			Mustad and products thereof
			Sesame seeds and products thereof
			Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of total SO <sub>2</sub>
			Lupin and products thereof
			Mollusc and products thereof

<sup>\*</sup>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 (120 mg)	
Energy	1685,71	KJ	2,006	KJ
	396,64	Kcal	0,472	Kcal
Fat	0	g	0	g
- saturated	0	g	0	g
Carbohydrates	99,16	g	0,118	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
Vitamin D3	mg	0,14	0,12	2800

\*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 <= 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	30.10.2018	by:	Dr. A. Lemke
on:			
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