Page 1 / 2 600441 Junai Him *60 caps Edition 1 Date 25 Feb 2025



JUNAI HIM ×60 CAPS

SPECIFICATIONS

1. PRODUCT INFORMATION

Product	
Name	Junai HIM x60 caps
Statute	Food supplement
Description	Hard capsules size "00"
Net weight	670 mg ± 10% (603.0 mg – 737.0 mg)
Gross weight	793 mg ± 10% (713.7 mg – 872.3 mg)
Declared product weight	42.8 g
Packing contains	60 capsules in 120 ml black Petpacker with black screw closure and a desiccant bag in a box
Instructions for use	Recommended daily intake is 2 x 1 capsule with a glass of water after a meal.
Instructions for use Shelf life	

2. INGREDIENTS

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Ingredients	Description	Declared value in 1 capsule	Quantity in 1 capsule
SUBSTANCES WITH	A NUTRITIONAL OR PHYSIOLOGICAL EFFE	ст	
L-arginine	• L-arginine (fermentation origin) [vegan]	250 mg	250 mg
Red Maca powder	 Red Maca (<i>Lepidium meyenii</i> Walp.) root powder Ratio plant/powder: 5 to 1 (concentration) Carrier: None 	200 mg	200 mg
L-citrulline	• L-citrulline (fermentation origin) [vegan]	100 mg	100 mg
Zinc	Zinc bisglycinate 28% buffered	5 mg	18 mg
Black pepper extract	 Black pepper (<i>Piper nigrum</i> L.) fruit extract Extraction solvents: Ethyl acetate Ratio plant/extract: 50-60 to 1 	2 mg	2 mg
Vitamin B6	Pyridoxine hydrochloride	1.4 mg	1.8 mg
OTHER INGREDIEN	TS		
VIVAPUR® 14	 Microcrystalline cellulose (bulking agent) 	93 mg	93 mg
Magnesium stearate	 Magnesium salts of fatty acids (anti-caking agent) 	5.2 mg	5.2 mg

3. INGREDIENTS IN DESCENDING ORDER

L-arginine, red maca (*Lepidium meyenii* Walp.) powder, hydroxypropyl methyl cellulose (capsule shell), L-citrulline, bulking agent: microcrystalline cellulose, zinc bisglycinate, anti-caking agent: magnesium salts of fatty acids, black pepper (*Piper nigrum* L.) fruit extract with 95% piperine, pyridoxine hydrochloride

4. CAPSULES PROFILE		
Product Size	00	
Name	HPMC Capsule Vegetable	
Net weight	123 mg ± 8 mg	
Cap/body composition	Hydroxypropyl methyl cellulose (HPMC)	
Per capsule (body/cap)	q.s.p. 100%	



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Page 2/2

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5.	HEAVY	METALS	PROFILE

Heavy metals	Specification
Cadmium	<1ppm
Lead	< 3 ppm
Mercury	< 0.1 ppm

6. MICROBIOLOGICAL PROFILE

Heavy metals	Specification
Total plate count / 1 g	< 105 CFU/g
Total yeast & mold / 1 g	< 103 CFU/g
Escherichia coli / 1 g	< 10 CFU/g
Staphylococcus aureus / 1 g	< 10 CFU/g
Salmonella / 25 g	negative
Listeria monocytogenes / 25 g	negative

7. REGULATORY STATEMENTS

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GMO Statement	This product is GMO FREE in accordance with Regulation (EC) 1829/2003, Regula- tion (EC) 1830/2003 and Commission Implementing Regulation (EU) 503/2013.
lonization Statement	This product has not been ionized in accordance with Directive 1999/2/EC and Directive 1999/3/EC concerning foods and food ingredients treated with ionizing radiation.
TSE/BSE Statement	This product is free from TSE/BSE substances according to Regulation (EC) 1069/2009.
Allergen Statement	This product doesn't contain allergen listed in Annex II of Regulation (EU) 1169/2011 and Commission Delegated Regulation (EU) 78/2014 amending Annexes II and III to Regulation (EU) 1169/2011.
Contaminants Statement	This product complies with Commission Regulation (EU) 2023/915 on maximum levels for certain contaminants in food.
Pesticide Statement	This product complies with the Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amend- ing Council Directive 91/414/EEC.
Gluten Statement	This product is "gluten free" meaning the level of gluten is below 20 mg/kg and complies with the Commission Implementing Regulation (EU) 828/2014 on the requirements for the provision of information to customers on the absence or reduced presence of gluten in food.
Additives Statement	This product complies with Regulation (EC) 1333/2008 on food additives, its modification, Commission Regulation (EU) 1130/2011 and specifications defined in Regulation (EU) 231/2012.
Nanomaterial Statement	This product is not produced using nanotechnology and is free from nanomate- rial, and so complies with Commission Recommendation 2011/696/EU.
Production Statement	This product is produced according to Regulation (EC) 852/2004 on the hygiene of foodstuffs.
Food Grade Statement	This product complies with the Regulation 178/2002 and its amendments.
Halal Compliance Statement	This product contains ingredients from plant and synthetic origin. It doesn't contain forbidden ingredients such as pork meat, insects or human enzyme de- rivatives. It is manufactured in equipment thoroughly cleaned at regular intervals. It can contain traces of ethanol, complying with the limits of European Pharma- copoeia. It doesn't contain narcotic and/or psychotropic substances.
Vegetarian/Vegan Statement	This product is suitable for vegetarians and vegans.
ETO Statement	This product complies with Commission Regulation (EU) 2022/1396 regarding ethylene oxide.

8. RESPONSIBLE PERSONS WHO APPROVED THIS DOCUMENT

QA/QC Manager Milica Madžarević

Head of R&D and David Držečnik, MSc. Pharm. Regulatory Affairs

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