TECHNICAL DATA SHEET & PRODUCT DOSSIER

MENOPAUSE CAPSULES

1. DOCUMENT CONTROL

Document title	Menopause_Technical Data Sheet
Product name	Menopause Capsules
Document number	FSC-TDS-002
Version	00
Prepared by	Rimante Jaseviciute
Signature	
Approved by	Sam Mallach
Signature	
Date of signing	2026 06 16

2. COMPANY DETAILS

Brand	Zelená Země s.r.o.
Address	Wuchterlova 523/5, 160 00 Praha 6
Contact	Lucie Garabášová
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3. PRODUCT IDENTIFICATION

Product Name	Menopause Capsules
Product type	Food supplement (Directive 2002/46/EC)
Regulatory type	Nutritional product
Pharmacological action	The product is not intended to diagnose, treat, cure, or prevent any disease.
Dosage Form	Capsules

Intended Use	Food supplement intended for oral use to support hormonal balance and well-being in women, particularly during menopause and peri-menopause.
Target Population	Adults
Route of administration	Oral
Recommended daily intake	2 capsules

4. FORMULA COMPOSITION

Hops extract (Humulus lupulus, flower), sodium hyaluronate (ExceptionHYAL® Star), vegetable capsule (hydroxypropyl methylcellulose), ashwagandha extract KSM-66® (Withania somnifera, root, 5% withanolides), red clover extract (Trifolium pratense L., aerial parts, 8% isoflavones), angelica extract (Angelica sinensis, root), lady's mantle extract (Alchemilla vulgaris, whole plant), sage extract (Salvia officinalis, herb and leaf, 2.5% rosmarinic acid), anti-caking agents: silicon dioxide, magnesium stearate; vitamin K2 (menaquinone-7, MenaQ7® Natural Matrix), rice flour, black cohosh extract (Cimicifuga racemosa, root), vitamin D3 (cholecalciferol), black pepper extract (Piper nigrum, fruits, BIOPERINE®), vitamin B6 (pyridoxine hydrochloride), vitamin B12 (methylcobalamin).

Ingredient	Amount in one capsule	Amount in recommended dose	% NRV*
Hops extract 4:1 (Humulus lupulus)	170 mg	340 mg	-**
Sodium hyaluronate (ExceptionHYAL® Star)	100 mg	200 mg	-**
Ashwagandha extract KSM-66® (5% withanolides)	40 mg	80 mg	-**
Red clover extract (8% isoflavones)	30 mg	60 mg	-**
Angelica extract 4:1	30 mg	60 mg	-**
Lady's mantle extract 10:1	30 mg	60 mg	-**
Sage extract 10:1 (2.5% rosmarinic acid)	30 mg	60 mg	-**
Black cohosh extract 4:1	5 mg	10 mg	-**
Black pepper extract 50:1 (BIOPERINE®)	1 mg	2 mg	-**
Vitamin B6	0.85 mg	1.7 mg	121.5 %
Vitamin K2 (MenaQ7® Natural Matrix 2000 ppm)	30 µg	60 µg	80 %
Vitamin D3	5 µg	10 µg	200 %
Vitamin B12	1.25 µg	2.5 µg	100 %

* % NRV - Nutrient Reference Value (EU).

** NRV not established.

5. ACTIVE INGREDIENT SPECIFICATIONS

Ingredient Name	Hops extract 4:1 (Humulus lupulus)
CAS number	84012-54-4
EC number	281-657-1
Origin	Botanical — dried flower heads (strobiles) of *Humulus lupulus* L. (Cannabaceae)
Technical data	Yellow-green to brown powder
Ingredient Name	Sodium hyaluronate (ExceptionHYAL® Star)
CAS number	9067-32-7
EC number	232-678-0
Origin	Biotechnological — produced by fermentation of Streptococcus zooepidemicus.
Technical data	White fine powder; highly hygroscopic; readily soluble in water
Ingredient Name	Ashwagandha extract KSM-66® (5% withanolides)
CAS number	90147-43-6
EC number	290-434-9
Origin	Botanical — root of Withania somnifera (L.) Dunal (Solanaceae); proprietary KSM-66® extraction process using only the root; standardised to 5% withanolides by HPLC
Technical data	Brownish-yellow powder; characteristic odour; min 5% withanolides
Ingredient Name	Red clover extract (Trifolium pratense, 8% isoflavones)
CAS number	84775-41-7
EC number	283-637-9
Origin	Botanical — aerial parts of *Trifolium pratense* L. (Fabaceae); hydroalcoholic extraction
Technical data	Light yellow to beige powder
Ingredient Name	Angelica extract 4:1 (Angelica sinensis)
CAS number	84775-41-7
EC number	Not assigned
Origin	Botanical — root of *Angelica sinensis* (Oliv.) Diels (Apiaceae)
Technical data	Light brown to beige powder
Ingredient Name	Lady's mantle extract 10:1-enriched yeast
CAS number	84776-95-4
EC number	Not assigned
Origin	Botanical — above-ground parts of *Alchemilla vulgaris* L. (Rosaceae)
Technical data	Light to medium amber liquid or powder
Ingredient Name	Sage extract 10:1 (2.5% rosmarinic acid) bisglycinate
CAS number	84082-79-1
EC number	Not assigned
Origin	Botanical — herb and leaf of Salvia officinalis L. (Lamiaceae); hydroalcoholic extraction; standardised 10:1 extract; min 2.5% rosmarinic acid
Technical data	Light green to grey-green powder; characteristic sage odour; rosmarinic acid and flavones as key constituents

Ingredient Name	Black cohosh extract 4:1 gluconate
CAS number	84776-26-1
EC number	283-459-1
Origin	Botanical — root of Cimicifuga racemosa (L.) Nutt. (Ranunculaceae); hydroalcoholic extraction; standardised 4:1 extract; triterpene glycosides (actein, cimicifugoside) as key constituents; EMA HMPC monograph established
Technical data	Light brown to brown powder; characteristic odour
Ingredient Name	Black pepper extract / BIOPERINE®
CAS number	94-62-2
EC number	202-350-5
Origin	Botanical — fruits of *Piper nigrum* L. and *Piper longum* L. (Piperaceae); BIOPERINE® is a proprietary extract
Technical data	Light tan to yellow powder; characteristic piperine odour
Ingredient Name	Vitamin K2 (menaquinone-7, MenaQ7® Natural Matrix 2000 ppm)
CAS number	863-61-6
EC number	212-740-6
Origin	Natural biotechnological — MenaQ7® is natural vitamin K2 as all-trans menaquinone-7 (MK-7), produced by *Bacillus subtilis natto* fermentation
Technical data	Yellow to orange oily substance or powder when on carrier; min 2000 ppm MK-7 on carrier
Ingredient Name	Vitamin D3
CAS number	67-97-0
EC number	200-673-2
Origin	Synthetic / semi-synthetic — produced by UV irradiation of 7-dehydrocholesterol derived from lanolin (sheep wool)
Technical data	White crystalline powder; practically insoluble in water; freely soluble in oils, fats, and ethanol
Ingredient Name	Vitamin B12
CAS number	13422-55-4
EC number	Not assigned
Origin	Biotechnological — produced by fermentation; methylcobalamin is the biologically active, co-enzyme form of vitamin B12
Technical data	Dark red crystalline powder
Ingredient Name	Vitamin B6
CAS number	58-56-4
EC number	200-603-0
Origin	Synthetic — produced by chemical synthesis
Technical data	White crystalline powder; practically insoluble in water; freely soluble in oils and fats; light-sensitive

6. EXCIPIENTS & CAPSULE SHELL

Vegetable capsule (hydroxypropyl methylcellulose), anti-caking agents: silicon dioxide, magnesium stearate; rice flour.

7. PHYSICOCHEMICAL CHARACTERISTICS

Appearance	Capsule size “0”
Colour	Transparent
Odour	No specific odour
Weight	Capsule weight: 600 mg including capsule (possible deviation ± 10%)
Packaging	150 ml brown glass jar with a 45 mm glossy black lid
Quantity in jar	60 capsules

8. MICROBIOLOGICAL SPECIFICATION

Parameter	Limit	Result
TAMC	< 1 000 CFU/g	Conforms
Salmonella sp.	Negative/25 g	Conforms
E. coli	Negative/1 g	Conforms

9. CONTAMINANT LIMITS

Parameter	Limit (mg/kg)	Reference (EU regulation)
Heavy metals		2023/915
- Lead	3	
- Mercury	0.1	
- Cadmium	1	
Pesticides	0.01 (depending on the pesticide residue)	396/2205
PAHs	10	2023/915
Pyrrolizidine alkaloids	400 microg/kg	2023/915

10.DIRECTIONS FOR USE

Take 2 capsules daily with a sufficient amount of water, preferably with a meal, or as directed by a healthcare professional. Do not exceed the recommended daily dose.

11. MANDATORY WARNINGS

Do not exceed recommended daily dose. Food supplements should not be used as a substitute for a varied diet. It is important to adhere to a balanced and varied diet and a healthy lifestyle. Keep out of reach of children.

12. STORAGE CONDITIONS

Store in a dry place at temperatures up to 25°C. Protect from direct sunlight. Keep out of reach of children. The manufacturer is not liable for damages caused by improper use or storage.

13. SHELF LIFE

Shelf life: 24 months when stored under recommended conditions and in the original sealed packaging. The best-before date is indicated on the packaging.

14. PACKAGING INFORMATION

Packaging type **Material** **Pack size** **Net quantity** **Primary packaging supplier**	150 ml brown glass jar with 45 mm glossy black lid; without sleeve

15. MANUFACTURING DATA

Manufacturer	AST Commerce & Co. s.r.o.
Certifications	Available upon request
GMP status	No
HACCP	Yes
ISO certificate	ISO 22716

16. REGULATORY STATUS

Physical and chemical requirements	The product complies with the requirements of Commission Regulation (EC) No. 2023/915, which sets maximum levels for certain contaminants in foodstuffs.
Allergens	We declare that the product does not contain any allergens as defined by Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers. The possibility of cross-contamination of the product during manufacturing and storage has been completely excluded based on hazard analysis.
GMO	In accordance with Regulations (EC) No. 1829/2003 and 1830/2003, the product does not contain GMOs and has not been produced from genetically modified raw materials.
Ionization	The product has not been treated with ionizing radiation as defined in Directive 1999/2/EC of the European Parliament and of the Council, as amended by Regulation (EC) No. 1137/2008.

17. TRACEABILITY

Batch coding format	First three letters represent product code. Next two digits are the sequential number of products made that year. Next to it expiry date appears.
Traceability status	Fully traceable
Recall procedure reference	Available upon request

18.QUALITY CONTROL RELEASE

Test	Specification	Method
Identity (appearance)	Conforms to description	Visual
Assay	90-110 % of label claim	HPLC or GC
Uniformity	Complies with Ph. Eur. 2.9.40	Mass variation or content uniformity
Microbiological quality (Ph. Eur. 5.1.4)	As described in Section 6	Microbial enumeration tests and tests for specified microorganisms
Heavy metals, pesticides, mycotoxins	As described in Section 7	ICP, HPLC, GC
Residual solvents	As per Ph. Eur. 2.4.24	HPLC, GC

19. SAFETY ASSESSMENT SUMMARY

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
Hops extract 4:1 / Humulus lupulus (flower)	Acute oral LD50 >2000 mg/kg bw (rat); not classified at supplemental doses; xanthohumol bitter acids low acute toxicity	Subchronic oral NOAEL >500 mg/kg bw/day (rat); no adverse hepatic or renal effects at supplemental doses; EMA HMPC monograph established	Not genotoxic; Ames test negative; xanthohumol tested negative for mutagenicity in standard bacterial assays	EMA HMPC: not recommended during pregnancy; no reproductive toxicity at supplemental doses; phytoestrogen activity (8-prenylnaringenin) — caution in oestrogen-sensitive conditions	Bitter acids and xanthohumol absorbed in small intestine; extensive hepatic first-pass metabolism; glucuronide and sulphate conjugates excreted renally; half-life ~8 hours	Safe at supplemental doses; EMA HMPC community herbal monograph established; not recommended during pregnancy or in oestrogen-sensitive conditions
Sodium hyaluronate / ExceptionHYAL® Star	Acute oral LD50 >1.77 g/kg (rat, IP); not classified at oral supplemental doses; well-established safety profile in food and cosmetics	No adverse effects at supplemental doses up to 200 mg/day in humans; 90-day rat NOAEL >1000 mg/kg bw/day (oral)	Not genotoxic; no mutagenic potential; Ames test negative; long established use in food and pharmaceutical applications	Not classified as reproductive toxicant; sodium hyaluronate is an endogenous glycosaminoglycan naturally present in connective tissue; no adverse reproductive effects	Partially absorbed in GI tract; low-MW fragments (< 50 kDa) absorbed; high-MW forms partially depolymerised in gut; degraded by hyaluronidase enzymes; eliminated renally	Safe at supplemental doses; GRAS status recognised; endogenous compound; no EFSA UL established; no safety concern identified

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
Ashwagandha extract KSM-66® / Withania somnifera (5% withanolides)	Acute oral LD50 >2000 mg/kg bw (rat, KSM-66®); not classified; multiple human clinical studies at 300–600 mg/day show no serious adverse effects	90-day oral NOAEL 1000 mg/kg bw/day (rat, KSM-66®); no adverse effects; KSM-66® has GRAS notification (GRN 000748, FDA 2020)	Not genotoxic; Ames test negative; no clastogenic activity identified for KSM-66® extract	Not recommended during pregnancy (uterotonic activity documented in animal studies); ANSES precautionary warning (2024); no reproductive toxicity at supplemental doses in non-pregnant adults	Withanolides absorbed in GI tract; hepatic metabolism via CYP450 enzymes; withanolide A and withaferin A have documented pharmacokinetics; renal and faecal excretion	Safe at supplemental doses (300–600 mg/day); not recommended during pregnancy; caution with thyroid medication and immunosuppressants; ANSES 2024 precautionary advisory applies
Red clover extract / Trifolium pratense (8% isoflavones)	Acute oral LD50 >2000 mg/kg bw (rat); not classified; isoflavones GRAS status in USA; long history of human consumption	Subchronic oral NOAEL >500 mg/kg bw/day (rat); no adverse effects at supplemental doses; EMA HMPC monograph established	Not genotoxic; isoflavones Ames test negative; no clastogenic activity identified	EMA HMPC: not recommended during pregnancy or in oestrogen-sensitive conditions (breast cancer, endometriosis, uterine fibroids); phytoestrogen activity via ER-α and ER-β binding	Isoflavones absorbed in small intestine after deconjugation by intestinal microbiota; metabolised to equol (individual variation); hepatic glucuronidation and sulphation; renal excretion	Safe at supplemental doses; EMA HMPC monograph established; not recommended during pregnancy, breastfeeding, or in oestrogen-sensitive conditions; equol production varies by individual
Angelica extract 4:1 / Angelica	Acute oral LD50 >2000 mg/kg bw	Subchronic oral NOAEL >300	Furanocoumarins (bergapten)	Not recommended	Ligustilide and ferulic acid	Safe at supplemental

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
sinensis (Dong Quai)	(rat); not classified at supplemental doses; ligustilide LD50 ~225 mg/kg (rat, IP) — not relevant at supplemental doses	mg/kg bw/day (rat); no adverse effects at supplemental doses; EMA assessment data available	present — phototoxic potential at high doses; not mutagenic in Ames test; no genotoxicity at supplemental concentrations	during pregnancy (uterotonic and emmenagogue properties documented); anticoagulant activity (coumarin content) — caution with warfarin and antiplatelet drugs	absorbed in GI tract; extensive hepatic first-pass metabolism; ferulic acid conjugated and excreted renally; furanodienone undergoes oxidative metabolism	doses; not recommended during pregnancy; anticoagulant drug interaction caution; avoid sun exposure at high doses due to furanocoumarin phototoxicity
Lady's mantle extract 10:1 / Alchemilla vulgaris (whole plant)	Acute oral LD50 >2000 mg/kg bw (rat); not classified; long traditional use with no documented serious acute toxicity	No specific NOAEL studies identified; subchronic use in humans at supplemental doses well-tolerated; EMA HMPC data available	Not genotoxic; tannin fraction (ellagitannins) tested negative in standard mutagenicity assays; no clastogenic activity	Not recommended during pregnancy (traditional contraindication); no specific reproductive toxicity data; tannin content may reduce iron absorption at high doses	Ellagitannins hydrolysed in GI tract to ellagic acid; further metabolised by gut microbiota to urolithins; flavonoids undergo hepatic glucuronidation; renal excretion	Safe at supplemental doses; EMA HMPC community herbal monograph established; not recommended during pregnancy; high tannin content may reduce mineral and drug absorption — separate dosing recommended
Sage extract 10:1 / Salvia officinalis (2.5% rosmarinic acid)	Acute oral LD50 >2000 mg/kg bw (rat); not classified at supplemental	Subchronic oral NOAEL >500 mg/kg bw/day (rat, extract); EMA	Not genotoxic; rosmarinic acid Ames test negative; carnosic	Not recommended during pregnancy (oestrogenic and	Rosmarinic acid absorbed in small intestine; hepatic methylation and	Safe at supplemental doses; EMA HMPC community

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
	doses; thujone content in essential oil fraction — neurotoxic at high doses, not relevant at extract supplemental levels	HMPC monograph established; thujone content in standardised extract is negligible	acid no mutagenic activity; no clastogenic activity identified for standardised extract	abortifacient properties documented in traditional use); EMA HMPC contraindication in pregnancy	glucuronidation; methyl-rosmarinic acid as primary metabolite; renal excretion within 24 hours	herbal monograph established; not recommended during pregnancy or during breastfeeding; epilepsy patients should avoid high doses (thujone)
Black cohosh extract 4:1 / Cimicifuga racemosa (root)	Acute oral LD50 >5000 mg/kg bw (rat); not classified at supplemental doses; EMA HMPC safety established	Subchronic oral NOAEL >900 mg/kg bw/day (rat, 90-day); EMA HMPC established acceptable daily intake; hepatotoxicity cases reported (rare — causality not confirmed)	Not genotoxic; triterpene glycosides Ames test negative; no clastogenic activity; long-term carcinogenicity studies show no tumorigenic potential	Not recommended during pregnancy or breastfeeding (EMA HMPC contraindication); not for use in patients with oestrogen-sensitive conditions (conflicting evidence); not for patients under 18 years	Triterpene glycosides partially absorbed; hepatic first-pass metabolism; actein and related glycosides detected in plasma; primarily faecal excretion; half-life ~1.5 hours	Safe at EMA HMPC recommended doses (40 mg/day standardised extract); not recommended in pregnancy; EMA HMPC duration of use: up to 6 months; hepatotoxicity monitoring recommended with long-term use; not for patients with liver disease
Vitamin K2 / Menaquinone-7 (MenaQ7®)	Acute oral LD50 >2000 mg/kg bw (rat); not	Subchronic oral NOAEL >45 mg/kg bw/day	Not genotoxic; menaquinone-7 Ames test	Not classified as reproductive toxicant; vitamin	Fat-soluble; absorbed in small intestine with	Safe at nutritional doses (75–180 µg/day); EFSA

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
	classified; natural vitamin K2 well-tolerated; EFSA positive opinion on MenaQ7® safety	(rat, 90-day, MenaQ7®); no adverse effects at nutritional doses; EFSA adequate intake 70 µg/day for adults	negative; no clastogenic activity; genotoxicity battery negative (MenaQ7® specific data)	K2 essential for normal coagulation and bone metabolism; EFSA no UL established	dietary fat; incorporated into chylomicrons; transported to liver and peripheral tissues; half-life of MK-7 ~72 hours (superior to MK-4 ~6 hours); stored in liver; excess excreted biliary and renally	adequate intake 70 µg/day; CRITICAL drug interaction — contraindicated with warfarin and coumarin anticoagulants; caution with antiplatelet therapy; no EFSA UL established
Vitamin D3 / Cholecalciferol	Acute oral LD50 >88 mg/kg bw (rat) — note: this corresponds to ~3.5 million IU/kg; CLP: Acute Tox. 1 (H300), Acute Tox. 1 dermal (H310), Acute Tox. 1 inhalation (H330), Aquatic Chronic 1 (H410) for pure substance — not applicable at supplemental	Subchronic oral NOAEL 0.1 µg/kg bw/day (rat); EFSA UL 100 µg/day (4000 IU) for adults; chronic excessive intake causes hypercalcaemia	Not genotoxic; Ames test negative; no clastogenic activity; genotoxic only at extreme supraphysiological doses	Not classified as reproductive toxicant at nutritional doses; essential for foetal bone development; excessive intake teratogenic (hypercalcaemia); EFSA UL applies during pregnancy	Fat-soluble; absorbed in small intestine with dietary fat; hydroxylated in liver to 25(OH)D3 (calcidiol); further hydroxylated in kidney to 1,25(OH)2D3 (calcitriol, active form); half-life of 25(OH)D3: ~3 weeks; excess stored in adipose tissue; metabolites	Safe at intended supplement doses (5–25 µg/day); EFSA UL 100 µg/day for adults; hypercalcaemia risk at >250 µg/day; monitor serum 25(OH)D3 with long-term high-dose use; note: PROHIBITED in EU cosmetics (Reg. 1223/2009 Annex II) — food

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
	doses of 5–25 µg/day				excreted biliary and renally	supplement use only
Vitamin B6 / Pyridoxine hydrochloride	Acute oral LD50 3700 mg/kg bw (rat); not classified at supplemental doses; water-soluble; excess excreted renally	90-day oral NOAEL 50 mg/kg bw/day (rat); EFSA UL 25 mg/day for adults; sensory neuropathy documented at doses >50 mg/day in humans	Not genotoxic; Ames test negative; no clastogenic activity; chromosomal aberration test negative	Not classified as reproductive toxicant; essential vitamin for foetal neural tube development; no adverse reproductive effects at supplemental doses; EFSA UL applies	Water-soluble; rapidly absorbed in small intestine; phosphorylated in liver to pyridoxal-5-phosphate (PLP, active form); pyridoxic acid as primary urinary metabolite; half-life ~25 days; no accumulation at normal doses	Safe at intended supplement doses; EFSA UL 25 mg/day for adults; peripheral sensory neuropathy documented at >50 mg/day in humans with chronic use; well within safe range at formula dose
Vitamin B12 / Methylcobalamin	Acute oral LD50 >2000 mg/kg bw (rat); not classified; water-soluble; excess excreted renally; no established toxic dose in humans	No adverse effects identified at any supplemental dose studied; EFSA no UL established; no toxicity identified even at pharmacological doses (1–2 mg/day)	Not genotoxic; Ames test negative; no clastogenic activity; no genotoxicity reported at any dose	Not classified as reproductive toxicant; essential vitamin for foetal neural development; deficiency during pregnancy causes neural tube defects; supplementation safe and recommended	Water-soluble; absorbed in ileum via intrinsic factor complex (active) and passive diffusion (high doses); methylcobalamin directly bioavailable as co-enzyme without hepatic conversion; stored in liver; excess excreted renally; half-life months to years	Safe at intended supplement doses; no EFSA UL established (no adverse effects identified); methylcobalamin preferred over cyanocobalamin for direct bioavailability and absence of cyanide moiety; no safety concern identified

Compound	Acute toxicity	Repeated-dose toxicity	Genotoxicity	Reproductive toxicity	Metabolism	Safety classification
Black pepper extract 50:1 / BIOPERINE® (95% piperine)	Acute oral LD50 514 mg/kg bw (rat); not classified at supplemental doses of 5–10 mg/day; wide margin between supplemental and toxic dose	Subchronic oral NOAEL 100 mg/kg bw/day (rat, 90-day); no adverse effects at supplemental doses; Sabinsa proprietary safety data package available	Ames test equivocal at very high doses in some bacterial strains; negative in mammalian cell genotoxicity assays; not classified as mutagen at supplemental doses	Not recommended during pregnancy — piperine shown to enhance placental permeability and may increase foetal exposure to co-administered substances; not classified as reproductive toxicant per se	Rapidly absorbed in GI tract; metabolised by CYP3A4 and UGT1A enzymes; inhibits intestinal P-glycoprotein and CYP3A4 — significant drug interaction potential increasing bioavailability of co-administered substances by 30–2000%; half-life ~6–8 hours; faecal and renal excretion	Safe at 5–10 mg/day; CRITICAL drug interaction caution — enhances bioavailability of co-administered drugs and supplements including warfarin, phenytoin, and cyclosporine; not recommended during pregnancy; do not use with narrow therapeutic index medications without medical supervision

20. FINAL LABEL TEXT

150 ml brown glass jar with 45 mm glossy black lid; without sleeve. The suitability of use and dosage of this preparation must be verified by the purchaser of the final product, in accordance with the applicable legislation in the relevant geographical territory. The manufacturer accepts no responsibility for the final labelling on product labels. Any labelling provided by the manufacturer is for guidance purposes only.

Manufacturers' recommendations on the labelling:

- Legislative name — "Food supplement" (the mandatory designation on EU-market supplement labels)
- This preparation is not intended to be used as a substitute for a varied diet. Keep out of reach of children. Store in a dry place at a temperature not exceeding 25°C, protected from direct sunlight and frost. The manufacturer accepts no liability for damage resulting from improper use or storage.
- Recommended dosage, including the statement: "Do not exceed…"
- Pack contents including weight
- Information indicating where the minimum durability date is stated (it is recommended to state — "on the packaging")
- Composition including the quantities of the main ingredients — quantities of ingredients to be stated per serving according to the dosage
- Seller — address including the country

21. DECLARATION OF COMPLIANCE

This product complies with applicable European Union legislation governing food supplements, food safety, labeling, and consumer protection.