

DTOX CAPS Brain & Balance Complex

(DDD = 5 capsules/day)

Document type: Evidence-Based Medicine (EBM) – structured evidence review

Intended audience: General practitioners, psychiatrists, neurologists

Product classification: Dietary supplement (adjuvant/supportive intervention)

1. Clinical Question (PICO)

Population (P)

Adults:

- experiencing increased psychological and neurocognitive burden (stress, anxiety, sleep disturbance, subjective cognitive fatigue / “brain fog”),
- with subjective cognitive complaints without diagnosed dementia,
- secondarily: patients using medical cannabis or THC (medical or non-medical), a population frequently presenting with sleep disturbance, anxiety, mood instability, cognitive complaints, and increased oxidative/stress load.

Intervention (I)

DTOX CAPS Brain & Balance Complex

DDD = 5 capsules/day, containing a combination of:

- adaptogens,
- nootropic compounds,
- antioxidants,
- mitochondrial cofactors,
- minerals and amino acids.

Comparator (C)

Placebo / standard care / other dietary supplements / no intervention.

Outcomes (O)**Primary outcomes:**

- stress and anxiety (validated scales),
- sleep quality,
- mood,
- subjective cognitive performance (memory, attention, executive function).

Secondary outcomes:

- fatigue, quality of life,
- safety and tolerability,
- adherence.

Exploratory (hypothesis-generating only):

- neuroregenerative support,
- modulation of the HPA stress axis,
- improvement of “cognitive hygiene” in THC users.

2. Literature Search Strategy

- Databases: **PubMed / MEDLINE, Cochrane Library, Scopus**
- Study types:
 - systematic reviews and meta-analyses,
 - randomized controlled trials (RCTs),
 - relevant observational studies when RCTs were unavailable.
- Keywords included:
Ashwagandha stress randomized,
L-theanine anxiety RCT,
Saffron depression meta-analysis,
Citicoline cognitive function randomized,
Hericium erinaceus mild cognitive impairment,
PQQ cognitive performance trial.
- Timeframe: predominantly 2005–2024
- Language: English (primary)

3. Daily Dose (DDD = 5 capsules)

Ingredient	Daily dose
Hericium erinaceus extract	800 mg
Ganoderma lucidum extract	650 mg
Ashwagandha KSM-66®	300 mg
L-theanine	200 mg
Citicoline	400 mg
Phosphatidylserine (20% powder)	300 mg (~60 mg PS)
Magnesium bisglycinate	200 mg
Vitamin C	100 mg
L-cysteine HCl	350 mg
Curcumin	25 mg
Piperine	5 mg
Saffron extract	30 mg
PQQ	10 mg
Coenzyme Q10	100 mg

4. Evidence Summary by Domain

4.1 Stress, Anxiety, Sleep – Highest Level of Evidence

Ashwagandha (*Withania somnifera*, KSM-66®)

- Multiple RCTs and systematic reviews.
- Consistent findings:
 - reduction of perceived stress and anxiety,
 - improvement of sleep quality,
 - occasional reduction of cortisol.
- **Level of evidence: MODERATE (GRADE B)**
- Note: 300 mg/day is clinically relevant; 600 mg/day is more commonly used in trials.

L-theanine

- RCTs demonstrate anxiolytic and relaxation effects without sedation.
- Improves focused attention in stressed individuals.
- **Level of evidence: MODERATE**

Saffron (*Crocus sativus*)

- Meta-analyses of RCTs in mild to moderate depression.
- Short-term efficacy comparable to SSRIs with superior tolerability.
- **Level of evidence: MODERATE–HIGH**

EBM conclusion:

Support of stress regulation, anxiety reduction, mood and sleep is the best-supported indication for this formulation.

4.2 Cognitive Function / “Brain Fog” – Moderate to Low Evidence

Citicoline

- RCTs show small to moderate improvements in memory and attention, especially in older adults.
- Heterogeneous results.
- **Level of evidence: LOW–MODERATE**

Hericium erinaceus

- Small RCTs in mild cognitive impairment.
- Temporary improvement of cognitive scores during supplementation.
- **Level of evidence: LOW–MODERATE**

PQQ

- Limited RCT data, often at higher doses (20 mg).
- Improvements in fatigue and selected cognitive domains.
- **Level of evidence: LOW**

EBM conclusion:

A mild cognitive benefit may be expected in selected individuals, particularly those with stress-related cognitive fatigue, but effects are not universal.

4.3 Neuroprotection / Oxidative Stress – Primarily Indirect Evidence

- **Reishi, curcumin, vitamin C, magnesium, CoQ10:**
 - strong biological plausibility,
 - limited direct clinical cognitive outcomes.
- **Level of evidence: LOW to VERY LOW**

EBM conclusion:

These components support mechanistic and preventive rationale, not therapeutic claims.

5. Medical Cannabis Context (EBM Interpretation)

- No RCTs evaluating this specific formulation in patients treated with medical cannabis.
- EBM-consistent formulation:
 - “The product may serve as a supportive nutritional intervention to improve stress regulation, sleep quality, and subjective cognitive well-being in patients for whom medical cannabis is part of therapy.”
- Claims regarding THC tolerance reduction:
 - ✗ Not evidence-based. May only be described as hypothesis-generating.

6. Safety and Interactions

- Overall good tolerability at stated doses.
- Consider:
 - piperine-related CYP/P-gp interactions,
 - additive sedative effects (with cannabis or CNS depressants),
 - individual sensitivity to adaptogens.

7. Strength of Recommendation

Indication	Recommendation
Stress, anxiety, sleep	Conditional recommendation
Subjective cognitive complaints	Weak recommendation
Adjunct to medical cannabis	Supportive, not standard therapy

8. Final EBM Conclusion

DTOX CAPS Brain & Balance Complex:

- **is EBM-defensible as a supportive dietary supplement,**
- **has the strongest evidence for stress, anxiety, sleep and mood support,**
- **offers limited but plausible cognitive benefits,**
- **does not replace pharmacotherapy and should not be presented as treatment.**