



COGNITIVE ENHANCEMENT AT ITS BEST*





Full spectrum extract with 9 Bioactives from *Bacopa monnieri*

WHAT IS BACOMIND®?

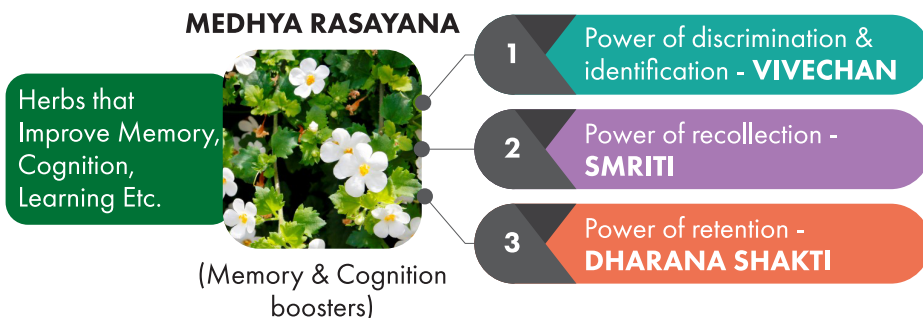
BacoMind® is a full spectrum extract containing 9 Bioactives of *Bacopa monnieri*.

BacoMind® is a scientifically developed, standardized phytochemical composition to maintain cognitive health at its best.

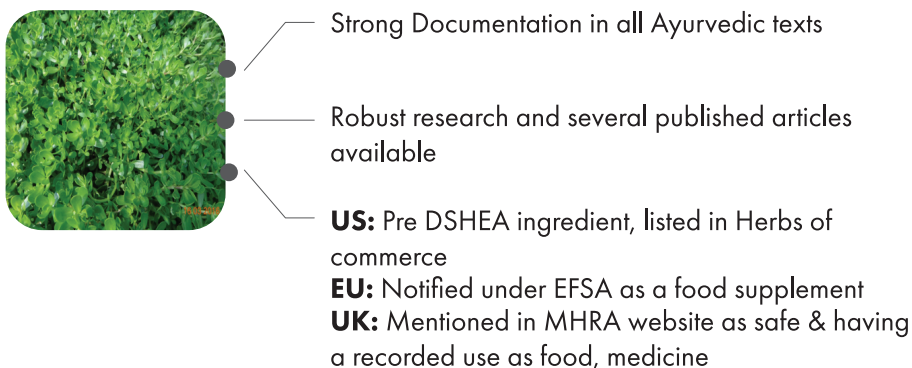
MEMORY – AN ELEMENTAL LINK FOR SOCIAL WELL BEING

Memory is important for social wellbeing. But, decline in memory and cognition is increasing worldwide. It has been estimated that, by the year 2040, about 81.1 million people will face problems relating to memory and cognition¹. The decline in memory however, can be managed by regular use of herbal nootropic ingredients.

HERBS THAT AID MEMORY & COGNITION – AYURVEDIC PERSPECTIVE²



BACOPA MONNIERI - THE BEST IN CLASS FOR MEMORY AND COGNITION



1. Ferri CP, Prince M, Brayne C, Brodaty H, Fratiglioni L, Ganguli M, Hall K, Hasegawa K, Hendrie H, Huang Y, Jorm A, Mathers C, Menezes PR, Rimmer E, Sczuzfca M; Alzheimer's Disease International. Global prevalence of dementia: a Delphi consensus study. *Lancet* 2005, 366(9503): 2112-2117.

2. Charaka Samhita

DEVELOPMENT OF BACOMIND®³⁻⁶

- 1 Control over biomass:** Geographical variations on percentage concentration of bioactive constituents were studied and the conclusions were integrated to have a control on quality of the biomass. The extract thus produced complies with international regulatory requirements relating to pesticides, heavy metals, polyaromatic hydrocarbons (PaH), mycotoxins and bacterial counts.
- 2 Chemistry of bacosides:** Research and developmental work carried out in-house led to structural classification of bacoside-A as a mixture of triterpene glycosides. Ambiguity over existence and structure of bacoside-B were highlighted and a HPLC method for analysis of bacoside-A was developed.
- 3 Bioassay guided fractionation:** A panel of bioassays was employed for identification of active constituents of *B. monnieri*. The knowledge gained was utilised to develop BacoMind® – A full spectrum extract standardised to contain 9 bioactive constituents
- 4 Soft extraction process:** A unique extraction process was developed to prevent degradation of active constituents and to retain the native chemistry of the plant in the extract.
- 5 Safety and efficacy evaluation:** BacoMind® was developed after careful evaluation of its safety and efficacy through preclinical and clinical studies.

3. Deepak M, Amit A. 'Bacoside B'-the need remains for establishing identity. *Fitoterapia* 2013, 87: 7-10.

4. Deepak M, Sangli GK, Arun PC, Amit A. Quantitative determination of the major saponin mixture 'Bacoside A' in *Bacopa monnieri* by HPLC, *Phytochemical analysis* 2005, 16(1): 24-29.

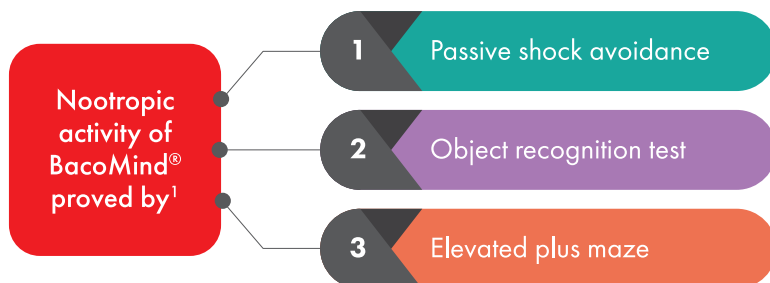
5. Deepak M, Amit A. The need for establishing identities of 'bacoside A and B', the major bioactive saponins of Indian medicinal plant *Bacopa monnieri*. *Phytomedicine* 2004, 11(2-3): 264-268.

6. D'Souza P, Deepak M, Rani P, Kadamboor S, Mathew A, Chandrashekar AP, Agarwal A. Brine shrimp lethality assay of *Bacopa monnieri*. *Phytotherapy Research* 2002, 16(2): 197-198.

STANDARDISATION OF BACOMIND®

- **BOTANICAL:** Macroscopic, Microscopic – Qualitative, Quantitative
- **PHYSICO CHEMICAL:** Colour, texture, moisture, ash
- **BIOLOGICAL:** Lipoyxygenase inhibition, Butyrylcholinesterase inhibition, ABTS radical scavenging & DPPH radical scavenging
- **PHYTOCHEMICAL:** HPLC, HPTLC, TLC for 9 Bioactives
 - Bacosine
 - Bacoside - A₃
 - Bacopaside I
 - Bacopaside II
 - Bacopasaponin C
 - Apigenin
 - Leuteolin
 - B - Sitosterol - D - Glucoside
 - Jujubogenin isomer of Bacopasaponin C

PRE-CLINICAL STUDIES OF BACOMIND®



BacominD® exhibited significant nootropic activity in the above three models of preclinical studies.⁷

CLINICAL STUDIES OF BACOMIND®

- **Trial - 01:** Memory enhancement in elderly participants - A double blind placebo controlled study
- **Trial - 02:** Improvement in memory performance in healthy older persons - A randomised placebo controlled double blind trial
- **Trial - 03:** BacominD®: A cognitive enhancer in children required Individual education program – An open labelled clinical trial
- **Trial - 04:** Improving Attention-Deficit Hyperactivity Disorder (ADHD) symptoms - An open labelled study

7. Kasture SB, Kasture VS, Joshua AJ, Damodaran A, Amit A. "Nootropic activity of BacominD, an enriched phytochemical composition from 'Bacopa monnieri'. Journal of Natural Remedies 2007, 7(1): 166-173.

Trial-01: Randomized Double Blind Placebo Controlled Clinical Study of BacoMind® on Age-Associated Memory Impairment in Elderly Participants⁸

Condition : AAMI: Age-associated memory impairment

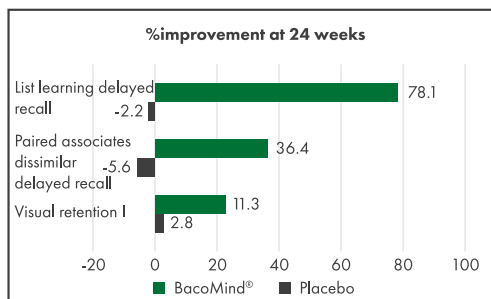
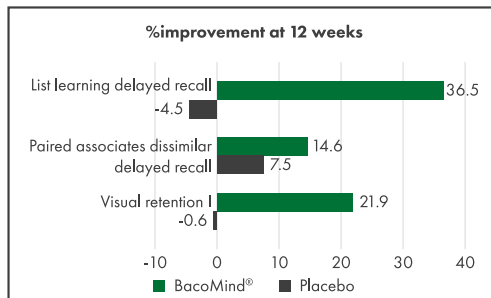
Dose : 450 mg/day

Participants : 65 elderly individuals (Age: 50-75 years)

Duration : 12 weeks

Evaluation : At 12 weeks and at 24 weeks (BacoMind® administered for 12 weeks only)

Outcome : BacoMind® improved cognitive functions such as attention and verbal memory in elderly individuals and was well tolerated



- BacoMind® showed significant ($p < 0.5$) improvement in List learning delayed recall, Paired associates dissimilar delayed recall and Visual retention I at 12 weeks and 24 weeks.

8. Barbhuiya HC, Desai RP, Saxena VS, Pravina K, Wasim P, Geetharani P, Allan JJ, Venkateshwartu K, Amit A. Efficacy and tolerability of BacoMind® on memory improvement in elderly participants-A double blind placebo controlled study. Journal of Pharmacology and Toxicology 2008, 3(6): 425-434.

Trial-02: Randomized Double Blind Placebo Controlled Clinical Study of BacoMind® on Normal Cognition in Healthy Elderly Individuals⁹

Condition : Normal Cognition in healthy elderly individuals

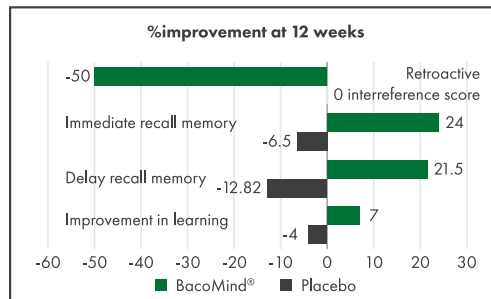
Dose : 300 mg/day

Participants : 98 elderly individuals (Age: ≥55 years)

Duration : 12 weeks

Evaluation : At 12 weeks

Outcome : BacoMind® improved memory acquisition and retention in healthy older Australians



- BacoMind® showed 50% improvement in the ability to recall information after a period of distraction as indicated by the reduction in the retroactive interference score.
- BacoMind® showed 24% improvement in the immediate recall memory.
- BacoMind® showed 21.5% improvement in easy recall of formerly acquired information with simultaneous retention of newer information.
- BacoMind® showed a significant positive improvement in learning.

9. Morgan A, Stevens J. Does *Bacopa monnieri* improve memory performance in older persons? Results of randomized, placebo-controlled double-blind trial. *The Journal of Alternative and Complementary Medicine* 2010, 16(7): 753-759.

Trial-03: Open-Label Clinical Study of BacoMind® on Children with Symptoms of Attention-Deficit Hyperactivity Disorder (ADHD)¹⁰

Condition : ADHD: Attention Deficit Hyperactivity Disorder

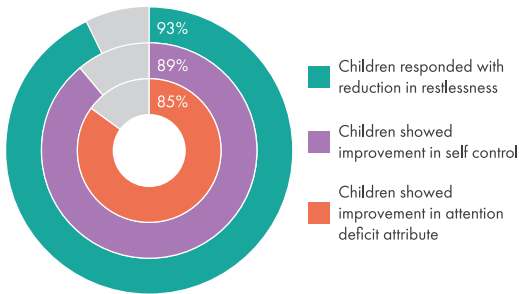
Dose : 225 mg/day

Participants : 27 children (Age: 6-12 years)

Duration : 6 months

Evaluation : At 6 months

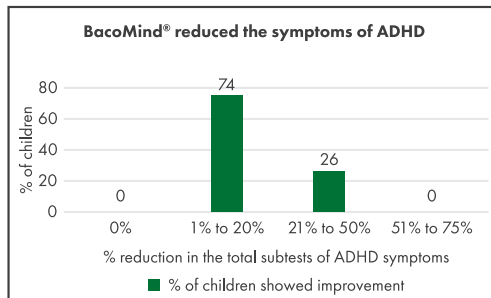
Outcome : BacoMind® significantly ($p < 0.05$) reduced the 6 out of 7 symptoms of ADHD in all children



Open labelled clinical studies with BacoMind® on children - ADHD

Additionally

- BacoMind® reduced learning problems in 78% of the children
- BacoMind® reduced Impulsivity in 67% of the children
- BacoMind® reduced psychiatric problems in 52% of the children



- BacoMind® reduced the ADHD symptoms in all children: 74% of the children showed up to a 20% reduction and 26% showed between 21% and 50% reduction in the total subtests scores.

10. Dave UP, Dingankar SR, Saxena VS, Joseph JA, Bethapudi B, Agarwal A, Kudiganti V. An Open-label Study to Elucidate the Effects of Standardized *Bacopa monnieri* Extract in the Management of Symptoms of Attention-deficit Hyperactivity Disorder in Children. *Advances in Mind-Body Medicine* 2014, 28(2):10-15.

Trial-04: Open-Label Clinical Study of BacoMind® in Children Requiring Individual Education Program (IEP)¹¹

Condition : Children requiring IEP

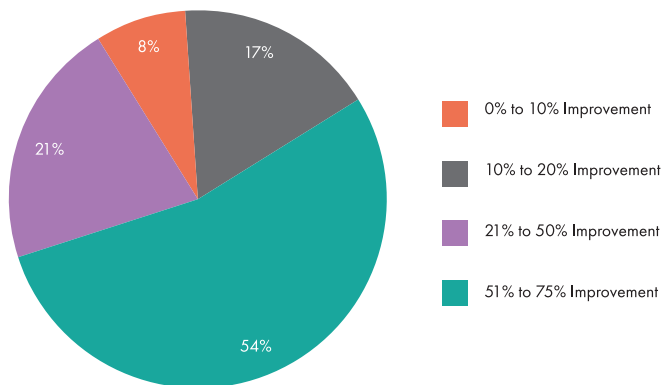
Dose : 225 mg/day

Participants : 24 children (Age: 4-18 years)

Duration : 4 months

Evaluation : At 4 months

Outcome : Children requiring IEP showed improvement in the battery of memory tests



- BacoMind® significantly ($p < 0.05$) improved short term verbal memory, working memory, visual memory, logical memory, mental control, auditory memory and memory related to personal life
- Overall, BacoMind® showed 51-75% improvement in 8% of the children, 21-50% improvement in 21% of the children and upto 20% improvement in 54% of the children in the total score of memory scale test.

11. Usha PD, Wasim P, Joshua JA, Geetharani P, Murali B, Mayachari AS, Venkateshwarlu K, Saxena VS, Deepak M, Amit A. BacoMind™: A cognitive enhancer in children requiring individual education programme. *Journal of Pharmacology and Toxicology* 2008, 3(4): 302-310.

SAFETY OF BACOMIND®

Documentation in Ayurvedic Books¹²

- Use as medicine
- Use of *Bacopa monnieri* in Ayurveda supports safety of BacoMind®

Phase 1 Clinical trial¹³

- No adverse effects reported

Animal Studies¹⁴

- Acute oral toxicity studies
- 14 day repeat dose oral toxicity
- 90 day repeat dose oral toxicity

BacoMind® well tolerated upto 500 mg/kg b.w* & NOAEL of 500 mg/kg b.w* established

In vitro Test¹⁵

- Bacterial reverse mutation test
- Chromosome aberration test
- Micronucleus test

BacoMind® is non-mutagenic

* Body Weight

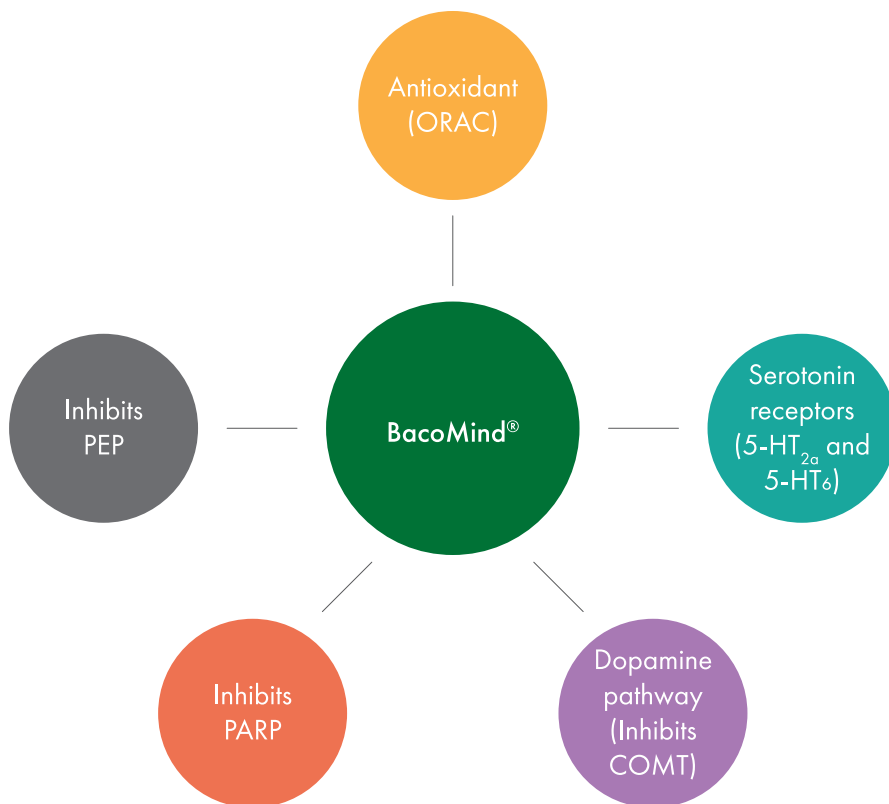
12. Charaka Samhita

13. Pravina K, Ravindra KR, Goudar KS, Vinod DR, Joshua AJ, Wasim P, Venkateshwarlu K, Saxena VS, Amit A. "Safety evaluation of BacoMind™ in healthy volunteers: a phase I study". *Phytomedicine* 2007, 14: 301-308.

14. Allan JJ, Damodaran A, Deshmukh NS, Goudar KS, Amit A. Safety evaluation of a standardized phytochemical composition extracted from *Bacopa monnieri* in Sprague Dawley rats. *Food and Chemical Toxicology* 2007, 45: 1928-1937.

15. Dipanwita DD, Preeti K, Dighe RP, Padmaja R, Anand MS, D'Souza P, Deepak M, Murali B, Amit A. In vitro safety evaluation and anticlastogenic effect of BacoMind™ on human lymphocytes. *Biomedical and Environmental Sciences* 2008, 21: 7-23.

MECHANISMS OF ACTION OF BACOMIND®¹⁶



Bacomind® seems to exert its cognitive health benefits possibly via different routes viz. dopaminergic pathway by inhibiting catechol-O-methyl transferase (COMT), serotonergic pathway by acting as antagonist of 5-HT_{2A} and 5-HT₆ receptors and neuroprotective mechanisms including antioxidant, inhibition of enzymes viz., poly (ADP-ribose) polymerase (PARP) and prolyl endopeptidase (PEP).

RECOMMENDED INTAKE OF BACOMIND®

Adults: 300 to 450 mg/day for 12 weeks or as directed by healthcare practitioner^{17,18}

Children: 225 mg/day for 16 weeks to 24 weeks^{19,20}

ACCREDITATIONS, CERTIFICATIONS & REGISTRATION FOR BACOMIND®

Quality



BUREAU
VERITAS

- ISO 22000:2005
- ISO 9001:2015
- BS OHSAS 18001:2007

Manufacturing Facility

- USFDA inspected site
- NSF Certified GMP Facility

Product



Australian
Patent

Product Registration

- ANVISA
- TGA

Other Credentials

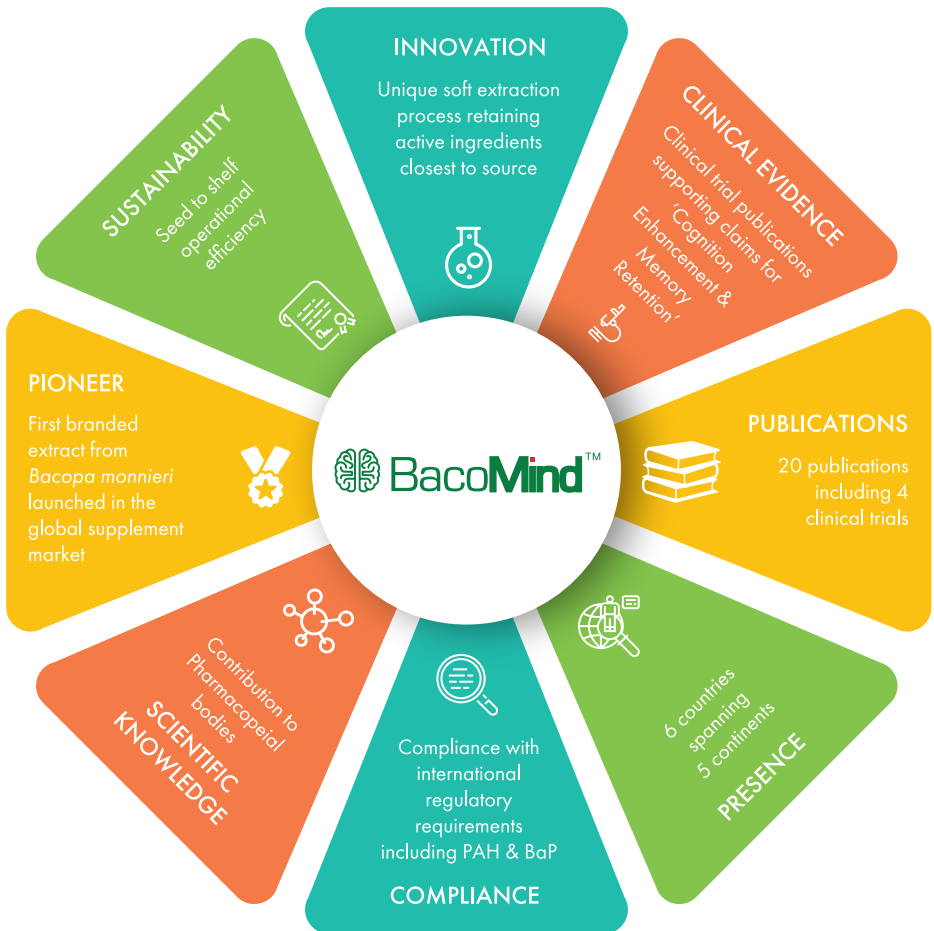
- Non GMO
- Non Irradiated
- Heavy metal complies USP limits
- Pesticide residue for PAH & BaP complies EU legislation

17. Barbhaiya HC, Desai RP, Saxena VS, Pravina K, Wasim P, Geetharani P, Allan JJ, Venkateshwarlu K, Amit A. Efficacy and tolerability of BacoMind® on memory improvement in elderly participants-A double blind placebo controlled study. *Journal of Pharmacology and Toxicology* 2008, 3(6): 425-434.
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20. Usha PD, Wasim P, Joshua JA, Geetharani P, Murali B, Mayachari AS, Venkateshwarlu K, Saxena VS, Deepak M, Amit A. BacoMind™: A cognitive enhancer in children requiring individual education programme. *Journal of Pharmacology and Toxicology* 2008, 3(4): 302-310.

BACOMIND® BENEFITS*

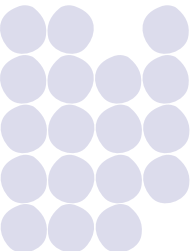
- Improves attention & verbal memory in older persons with Age Associated Memory Impairment
- Improves self-control, attention and reduces restlessness in children with ADHD
- Improves learning & memory in children requiring Individual Education Program

WHY CHOOSE BACOMIND®



*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease





BacoMind™



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