

# MindEase *affron*<sup>®</sup>

## Mood-Support Formula with Standardized Saffron Extract

MindEase is a formula that contains the clinically studied, **patented extract of genetically tested *affron*<sup>™</sup> *Crocus sativa* extract**, demonstrating positive effects for **mood, sleep, and perimenopausal symptoms**. MindEase contains the researched daily dose of 28 mg *affron*<sup>™</sup> extract and includes other supportive nutrients for mood, **nervousness**, and **emotional fatigue**, including 5-HTP, pyridoxal-5'-phosphate, and magnesium bisglycinate at 100 mg, 30 mg, and 100 mg daily dose, respectively.

### Clinical Studies on *affron*<sup>™</sup>

In a randomized, double-blind, placebo-controlled study, 128 participants with self-reported low mood were given *affron*<sup>™</sup> (22 mg/d or 28 mg/d) or a placebo, for 4 weeks. On the POMS Total Mood Disturbance scale, **stress, negative mood, and anxiety were significantly reduced compared to placebo** with the 28 mg/d dose ( $p < 0.001$ ,  $d = -1.10$ ), but these results were not achieved with the 22 mg/d dose.<sup>[1]</sup>

In a randomized, double-blind, placebo-controlled study, 68 participants aged 12–16 years with self-reported mild to moderate depression or anxiety were given *affron*<sup>™</sup> (14 mg twice daily) or a placebo, for 8 weeks. *affron*<sup>™</sup> was associated with greater **improvements in overall internalizing symptoms, separation anxiety, social phobia, and depression** ( $p = 0.049$ ,  $0.003$ ,  $0.023$ , and  $0.016$ , respectively). Total internalizing scores decreased by an average of 33% compared to 17% in the placebo group ( $p = 0.029$ ).<sup>[2]</sup>

In a randomized, double-blind, placebo-controlled study, 139 participants with persistent depression, undergoing pharmacotherapy, were given *affron*<sup>™</sup> (14 mg twice daily) or a placebo, for 8 weeks. Based on the clinician-rated Montgomery-Åsberg Depression Rating Scale, **depressive symptoms reduced by 41% in the saffron group and 21% in the placebo group** ( $p = 0.001$ ). There were no between-group differences for the self-reported scale and for quality-of-life scale.<sup>[3]</sup>



In a randomized, double-blind, placebo-controlled study, 120 participants with unsatisfactory sleep were given *affron*<sup>™</sup> (14 mg or 28 mg) or a placebo, one hour before bed. Compared to placebo, saffron was associated with **improved sleep quality and better mood on waking**.<sup>[4]</sup>

In a parallel-group, double-blind, placebo-controlled study, 82 participants experiencing **perimenopause symptoms** were given *affron*<sup>™</sup> (14 mg twice daily) or a placebo, for 12 weeks. On the POMS Total Mood Disturbance scale, **stress, negative mood, and anxiety were significantly reduced** compared to placebo ( $p < 0.001$ ,  $d = -1.10$ ), but no effect with the 22 mg dose.<sup>[5]</sup>

An animal, in vivo study demonstrated that *affron*<sup>™</sup> extract was congruent with behavioural changes congruent with improvements in anxiety and depression, including motivation and anhedonia.<sup>[6]</sup>

In a randomized, double-blind, placebo-controlled study, 62 adults engaging in physical activity were randomly assigned to either 28 mg of saffron extract or a placebo, for 6 weeks. The goal of the study was to determine the influence on *affron*<sup>™</sup> on mood states and physiological effects in exercising adults. No between-group differences were observed; however, when analyzed by sex, there was a **significant increase in exercise enjoyment** ( $p = 0.009$ ) and **heart-rate variability** ( $p = 0.001$ ) in men compared to women.<sup>[7]</sup>

The first company in the industry to have invested in an ISO 17025-accredited laboratory to test for identity, potency, oxidation, disintegration, purity, and more.



## References

- 1 Kell, G., A. Rao, G. Beccaria, P. Clayton, A.M. Inarejos-García, and M. Prodanov. "affron® a novel saffron extract (*Crocus sativus* L.) improves mood in healthy adults over 4 weeks in a double-blind, parallel, randomized, placebo-controlled clinical trial." *Complementary Therapies in Medicine*, Vol. 33 (2017): 58–64.
- 2 Lopresti, A.L., P.D. Drummond, A.M. Inarejos-García, and M. Prodanov. "affron®, a standardised extract from saffron (*Crocus sativus* L.) for the treatment of youth anxiety and depressive symptoms: A randomised, double-blind, placebo-controlled study." *Journal of Affective Disorders*, Vol. 232 (2018): 349–357.
- 3 Lopresti, A.L., S.J. Smith, S.D. Hood, and P.D. Drummond. "Efficacy of a standardised saffron extract (affron®) as an add-on to antidepressant medication for the treatment of persistent depressive symptoms in adults: A randomised, double-blind, placebo-controlled study." *Journal of Psychopharmacology*, Vol. 33, No. 11 (2019): 1415–1427.
- 4 Lopresti, A.L., S.J. Smith, and P.D. Drummond. "An investigation into an evening intake of a saffron extract (affron®) on sleep quality, cortisol, and melatonin concentrations in adults with poor sleep: A randomised, double-blind, placebo-controlled, multi-dose study." *Sleep Medicine*, Vol. 86 (2021): 7–18.
- 5 Lopresti, A.L., and S.J. Smith. "The effects of a saffron extract (affron®) on menopausal symptoms in women during perimenopause: A randomised, double-blind, placebo-controlled study." *Journal of Menopausal Medicine*, Vol. 27, No. 2 (2021): 66–78.
- 6 Orio, L., F. Alen, A. Ballesta, R. Martin, and R. Gomez de Heras. "Antianhedonic and antidepressant effects of affron®, a standardized saffron (*Crocus sativus* L.) extract." *Molecules*, Vol. 25, No. 14 (2020): 3207.
- 7 Lopresti, A.L., and S.J. Smith. "An examination into the mental and physical effects of a saffron extract (affron®) in recreationally-active adults: A randomized, double-blind, placebo-controlled study." *Journal of the International Society of Sports Nutrition*, Vol. 19, No. 1 (2022): 219–238.

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Pharmactive Biotech Products, S.L.U.

### Each vegetable capsule contains:

Magnesium (from 384 mg of magnesium bisglycinate) . . . . .	50 mg
5-Hydroxy-L-tryptophan ( <i>Griffonia simplicifolia</i> seed isolate) . .	25 mg
Vitamin B6 (pyridoxal-5'-phosphate) . . . . .	15 mg
Saffron ( <i>Crocus sativus</i> ) stigma extract (affron™), standardized to 3.5% Lepticrosalides™, providing crocins and safranal . . . .	14 mg

**Nonmedicinal ingredients:** Vegetable magnesium stearate, microcrystalline cellulose, and silicon dioxide in a non-GMO vegetable capsule composed of vegetable carbohydrate gum and purified water.

**Directions of use: Adults:** Take 2 capsules daily or as directed by your health-care practitioner.

**Duration of use:** Consult a health-care practitioner for use beyond 12 weeks.

**Cautions and warnings:** Avoid taking with alcohol or products that cause drowsiness. Consult a health-care practitioner if symptoms persist or worsen. Consult a health-care practitioner prior to use if you are taking carbidopa or drugs/supplements with serotonergic activity—these may include, but are not limited to, L-tryptophan, S-adenosylmethionine (SAME), St. John's wort, antidepressants, pain killers, over-the-counter cough and cold medication containing dextromethorphan, anti-nausea medication, and antimigraine medication—if you suffer from any psychological disorder or condition such as frequent anxiety or depression; or if you are taking antidepressants. Discontinue use and consult a health-care practitioner if you show signs of weakness, oral ulcers, abdominal pain accompanied by severe muscle pain, or skin changes.

**Contraindications:** Do not use this product if you have scleroderma; if you are pregnant or breast-feeding; if you are taking blood thinners/anticoagulants; or if you have a bleeding disorder.

**Known adverse reactions:** Some people may experience diarrhea, nausea, vomiting, abdominal pain, or drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle, or involved in activities requiring mental alertness. Some people may experience anxiety/nervousness, increased appetite, nausea, or headache; in which case, discontinue use.

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