FORMULATION CONCEPT SPRINT

Daily supplement formula for mild-to moderate premenstrual symptoms

EU/UK authorised ingredients assessment with compliant, defensible dosage and claims.

SAMPLE DELIVERABLE · ILLUSTRATIVE ANONYMISED EXAMPLE

The concept name is fictional; the ingredients, doses, evidence, and references are real and current as of July 2026.

Concept (example): "CycleCalm - PMS Support" - daily capsule
Target: mild-to-moderate cyclical PMS
Markets: EU & Great Britain

Brief

The concept is for a daily supplement intended for women experiencing mild to moderate premenstrual symptoms: low mood, irritability, breast tenderness, bloating, and fluid retention.

Objective: to develop a formulation comprising ingredients whose efficacy has been conclusively demonstrated by clinical trials in humans, thereby enabling claims on the packaging that comply with regulatory requirements. If the most compelling evidence of an ingredient's efficacy cannot be stated on the packaging, it is labelled in a specific manner to ensure consistency between the marketing strategy and the formulation.

Scope of work: concept and data justification only, selection of ingredients, dosage, and mechanism of action. Does not include laboratory samples, stability studies, or research and development work in the field of manufacturing.

Proposed actives

1. **Vitamin B6 (pyridoxal-5-phosphate) - 10–12 mg/day**

Rationale: cofactor for synthesis of serotonin, GABA, and dopamine - the mood/irritability axis of PMS. This is the anchor active: the one ingredient that is both trial-supported for PMS and carries authorised claims. Dosed within the EFSA 2023 upper limit.

Evidence: systematic review of 9 randomised controlled trials (940 women) - odds ratio 2.32 for symptom relief.

On-pack claim status: Claimable: "regulation of hormonal activity" and "normal psychological function".

2. **Magnesium (bisglycinate) - 200 mg/day**

Rationale: modulates NMDA / neuromuscular activity; pairs with B6 for anxiety-type symptoms and eases fluid retention. Well-tolerated organic form.

Evidence: RCT - 200 mg magnesium plus 50 mg B6 reduced anxiety-related PMS; magnesium 200 mg reduced fluid-retention symptoms.

On-pack claim status: Claimable: "reduction of tiredness and fatigue" and "normal psychological function".

3. **Calcium (citrate) - 500-600 mg/day**

Rationale: cyclical calcium fluctuations track PMS severity; supplementation reduced luteal-phase symptoms in a large RCT. Contributes toward the ~1200 mg/day total (diet plus supplement) used in trials.

Evidence: RCT (466 women) - 1200 mg/day cut the luteal symptom score.

On-pack claim status: Evidence-only: calcium carries a bone claim, not a PMS claim.

4. **Vitex agnus-castus (standardised fruit extract, Ze 440-type) - ~4 mg extract/day**

Rationale: dopaminergic (D2) action lowers prolactin, the best-evidenced botanical for PMS, targeting breast tenderness and mood. Strong efficacy, but see claim status and contraindications.

Evidence: RCT (170 women); supported by a systematic review and meta-analysis.

On-pack claim status: Evidence-only - botanical claims are "on hold" (not authorised).

Evidence-only = strong human evidence for the PMS benefit, but no authorised EU/GB on-pack claim for that benefit. Include for efficacy; keep on-pack wording to the authorised nutrient claims (B6, magnesium).

The science-vs-claims bridge

This is the decision that makes or breaks the product. Two of the four actives (B6, magnesium) carry authorised claims you can print. The other two (calcium for PMS, Vitex) deliver much of the felt benefit but cannot be described on-pack for that purpose: calcium only has a bone claim, and botanical claims are "on hold". A credible product, therefore, leads its on-pack story with B6 and magnesium, uses calcium and Vitex to actually work, and never states a PMS or menstrual benefit it can't defend.

Suggested compliant on-pack set: "Vitamin B6 contributes to the regulation of hormonal activity" · "Vitamin B6 contributes to normal psychological function" · "Magnesium contributes to a reduction of tiredness and fatigue" · "Magnesium contributes to normal psychological function." Each requires the product to be a source of that nutrient (at least 15% NRV per daily dose - comfortably met here).

Safety and contraindications

- **Vitamin B6 upper limit.** EFSA reduced the tolerable upper intake level to 12 mg/day for adults in 2023 (from 25 mg), on peripheral-neuropathy grounds. The PMS trials used up to 100 mg/day, which now exceeds the EU limit, so this concept deliberately doses within the UL and does not chase the trial doses.
- **Vitex agnus-castus.** Contraindicated in pregnancy and breastfeeding. Caution with hormonal and dopaminergic medicines, including oral contraceptives (possible reduced efficacy), and in pituitary disorders. Requires a clear on-pack caution and "consult a healthcare professional" wording.
- **Calcium.** Keep total intake (diet plus supplement) within safe limits; citrate is chosen for tolerability and absorption independent of stomach acid.
- **General.** Not intended to prevent, treat, or cure any condition; positioned as nutritional support for women with cyclical symptoms.

Reference pack

1. Wyatt KM, Dimmock PW, Jones PW, O'Brien PMS. Efficacy of vitamin B-6 in the treatment of premenstrual syndrome: systematic review. BMJ 1999;318(7195):1375–81.
2. EFSA NDA Panel. Scientific opinion on the tolerable upper intake level for vitamin B6. EFSA Journal 2023;21(5):8006. (UL 12 mg/day, adults.)
3. Thys-Jacobs S, Starkey P, Bernstein D, Tian J. Calcium carbonate and the premenstrual syndrome. Am J Obstet Gynecol 1998;179(2):444–52.
4. De Souza MC, Walker AF, Robinson PA, Bolland K. A synergistic effect of 200 mg magnesium plus 50 mg vitamin B6 for anxiety-related premenstrual symptoms: randomised, double-blind, crossover study. J Womens Health Gend Based Med 2000;9(2):131–9.
5. Walker AF, De Souza MC, Vickers MF, et al. Magnesium supplementation alleviates premenstrual symptoms of fluid retention. J Womens Health 1998;7(9):1157–65.
6. Schellenberg R. Treatment for the premenstrual syndrome with agnus castus fruit extract: prospective, randomised, placebo-controlled study. BMJ 2001;322(7279):134–7.
7. Verkaik S, Kamperman AM, van Westrhenen R, Schulte PFJ. The treatment of premenstrual syndrome with preparations of Vitex agnus castus: a systematic review and meta-analysis. Am J Obstet Gynecol 2017;217(2):150–66.

Disclaimer

Illustrative sample only. The concept name is fictional; the ingredients, doses, evidence, and references are real and accurate as of July 2026. This is a formulation and evidence rationale for a brand, not medical advice, and not a substitute for regulatory sign-off, safety/stability testing, or manufacturer due diligence before launch.