

## FACT SHEET - IMUNI Sleep + Mind Balance

### What is IMUNI Sleep + Mind Balance?

Designed for your peace of mind, this comprehensive specialised combo contains 4 key herbal supplements which are: Lavender oil, Lemon balm, Passionflower and Saffron designed to help support healthy mood balance and are traditionally used in Western herbal medicine to relieve symptoms of mild anxiety and stress, relieve sleeplessness and reduce time to fall asleep; and support healthy sleeping patterns.

This evidence-based formulation combines of KSM-66® Ashwagandha and safr'inside™ Saffron, with British Pharmacopoeia grade lavender oil, and herbal extracts of passionflower and lemon balm.

### Ingredients:

Each vegan capsule contains:

- Lavender oil 40mg
- Crocus sativus (Saffron) stigma ext. dry conc. 15mg from dry stigmas 75mg
- Melissa officinalis (Lemon Balm) leaf ext. dry conc. 187.5mg from dry leaf 750mg
- Passiflora incarnata (Passionflower) herb top flowering ext. dry conc. 100mg from herb top flowering 2g
- Withania somnifera (Ashwagandha) root ext. dry conc. 300mg from dry root 3.75g

All ingredients are vegetarian and vegan friendly. This product does not contain animal products, dairy, lactose, gluten, nuts or genetically modified ingredients (GMO-free).

### Recommended dose:

ADULT DOSE: Take one capsule twice daily with food or as recommended by your healthcare practitioner.

### Precautions/contraindications:

Consult your doctor or pharmacist before use if:

- You are pregnant, breastfeeding, or preparing for pregnancy.
- You are using medication/s for diabetes, high blood pressure, thyroid disorders, or sedative medications.
- You have previously experienced anaphylaxis to any medication or supplement.

### Warnings and adverse effects:

- If symptoms persist or worsen consult your healthcare professional.
- Store below 25°C in a cool, dry place away from direct heat and sunlight.
- Do not use if tamper evidence seal is broken or missing.
- Allergic reactions and anaphylaxis are possible with any medication or supplement. Seek urgent medical attention if you experience symptoms of skin rash, wheezing, shortness of breath or difficulty breathing.

## Lavender oil:

- Lavender oil is generally well tolerated.
- Gastrointestinal side effects (nausea, diarrhoea, constipation, indigestion), headache and sedation are possible side effects.
- There is currently insufficient reliable evidence to ensure safety in pregnancy and lactating women.

## Saffron:

- Saffron extract is generally well tolerated. Mild gastrointestinal adverse effects are possible (e.g. nausea).
- Severe allergic reactions e.g. anaphylaxis is possible, but rare.
- Large doses of saffron (in excess of what is normally consumed in foods) is unsafe for use in pregnancy.

## Lemon Balm:

- Lemon balm is generally well tolerated. Wheezing has been rarely reported.
- Lemon balm has Generally Recognized as Safe (GRAS) status in the United States.
- There is currently insufficient reliable evidence to ensure safety in pregnancy and lactating women. We recommend avoiding use if you are pregnant, preparing for pregnancy, or breastfeeding.

## Passionflower:

- Passionflower is generally well tolerated.
- Dizziness, confusion, and sedation have been reported in some clinical trials. However, these events generally do not necessitate discontinuation
- Passionflower might be unsafe for use in pregnancy. Avoidance is recommended for pregnant or breastfeeding women, or women planning pregnancy.

## Ashwagandha:

- Ashwagandha is generally well tolerated.
- Diarrhea, gastrointestinal upset, nausea, and vomiting is possible. However, these adverse effects do not commonly occur with typical doses.
- Ashwagandha might be unsafe for use in pregnancy. Avoidance is recommended for pregnant or breastfeeding women, or women planning pregnancy.

## **For Health Professionals:**

### **Interactions with medications:**

#### Lavender oil:

- There is a theoretical risk of lavender oil having an additive effect with drugs or medications that suppress the central nervous system (CNS suppressants). IMUNI therefore recommends precaution when intending to use Lemon Balm in conjunction with substances like alcohol, benzodiazepines, and other sedative drugs.

## Saffron:

- Theoretically, Saffron might have additive effects when used in combination with anti-hypertensive (blood pressure lowering) or antidiabetes drugs (might increase the risk of hypoglycaemia or low blood sugar).
- Theoretically, Saffron might have additive sedative effects if used in conjunction with sedative drugs or substances.

## Lemon Balm:

- There is a theoretical risk of lemon balm having an additive effect with drugs or medications that suppress the central nervous system (CNS suppressants). IMUNI therefore recommends precaution when intending to use Lemon Balm in conjunction with substances like alcohol, benzodiazepines, and other sedative drugs.
- There is a theoretical risk of Lemon Balm interfering with thyroid replacement therapy (e.g. thyroxine). Precaution and close monitoring of thyroid function is advised.

## Passionflower:

- Use of passion flower with sedative drugs might cause additive effects and side effects. Precaution is advised.

## Ashwagandha:

- Theoretical drug interactions are possible with the following drugs:
  - Anti-diabetes drugs: possible increased risk of hypoglycaemia (low blood sugar).
  - Anti-hypertensive drugs: possible increased risk of hypotension (low blood pressure).
  - Benzodiazepines (e.g. diazepam, temazepam): possible increased sedative effect.
  - Immunosuppressants: Ashwagandha might have immunostimulating effects and there is a theoretical concern that it might decrease effectiveness of immunosuppressants.
  - Thyroid hormone: might increase the therapeutic and adverse effects of thyroid hormone treatment. Ashwagandha might boost thyroid hormone synthesis and secretion.

## References:

- TRC Natural Medicines Database [Internet]. TRC Healthcare [cited 03 Nov 2021]. Available from: TRC Natural Medicines Database <https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements>