

# Food supplements containing melatonin are not suitable for everyone!

**Under the national nutrivigilance scheme run by ANSES, reports of adverse effects likely to be associated with the consumption of food supplements containing melatonin have been reported. A retrospective analysis of these reports, combined with the considerable level of consumption of this type of supplement, led ANSES to conduct an assessment of the potential health risks. On 11 April, ANSES published an opinion on the risks associated with the consumption of food supplements containing melatonin (see link below).**

In France, melatonin is used in medicinal products, extemporaneous preparations and food supplements. It is a hormone secreted naturally during the night. One of its physiological functions is to promote sleep. In addition to its effects on the biological clock, melatonin has other properties: modulation of mood and the immune system, regulation of body temperature and intestinal motility. It also has vasodilatory, vasoconstrictor and proinflammatory activity. Under certain circumstances, or when interacting with other substances, these physiological effects can lead to the occurrence of adverse effects.

Ninety cases of adverse effects following the intake of food supplements containing melatonin have been reported to the national nutrivigilance scheme. Each case has been analysed individually and the conclusions shared with the parties reporting the cases and the manufacturers. A variety of different effects have been reported: general symptoms (headaches, dizziness, drowsiness, nightmares, irritability) and neurological (tremors, migraine) and digestive (nausea, vomiting, abdominal pain) disorders.

The retrospective analysis of all these cases led ANSES to initiate an assessment of the risks associated with the consumption of these food supplements. The risks were characterised by an in-depth analysis of the literature, leading ANSES to issue recommendations for manufacturers/producers, consumers and healthcare professionals.

## The Agency's recommendations for consumers

The Agency recommends that people suffering from inflammatory or autoimmune diseases, as well as pregnant and breastfeeding women, children and adolescents, and anyone carrying out any activity requiring sustained vigilance where drowsiness could pose a safety problem, should not consume melatonin in the form of a food supplement.

People with epilepsy, asthma, or suffering from mood, behaviour or personality disorders, or anyone being treated with medication should seek medical advice regarding the consumption of melatonin in the form of food supplements.

In the absence of sufficient data on the long-term effects of melatonin consumption, the Agency recommends limiting the consumption of these food supplements to occasional use.

More generally, the Agency recommends that consumers seek medical advice before consuming food supplements and inform their doctor that they are taking any food supplements.

## Other recommendations

French regulations authorise the marketing of food supplements providing less than 2 mg of melatonin per day. Given the variability in the status of melatonin and the regulatory limits governing its use within the European Union, and in the absence of sufficient data on the safety of daily consumption of 2 mg of melatonin, the Agency has questions about the place of melatonin on the market in food supplement form at doses comparable to those of the medicinal product. It believes it is necessary to define a harmonised regulatory framework at European level on the basis of safety studies conducted for doses below 2 mg.

More generally, ANSES reminds healthcare professionals of the need to report to the national nutrivigilance scheme any adverse effects likely to be associated with the consumption of food supplements about which they become aware.

Lastly, ANSES emphasises the value of setting up a joint international project on the monitoring of adverse effects associated with the consumption of food supplements.

**Gwenn VO VAN REGNAULT (Anses)**

## TO FIND OUT MORE, VISIT:

[Opinion of the French Agency for Food, Environmental and Occupational Health & Safety on the risks associated with the consumption of food supplements containing melatonin](#)