

6723-MELATONIN PHARMA**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1. Identification of the substance or preparation**

Name: Melatonin.

Bulk code: 6723

1.2. Synonyms

Melatoniini, Melatoninum.

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White or almost white.

3. COMPOSITION/INFORMATION ON COMPONENTSFormula: $C_{13}H_{16}N_2O_2$

CAS No: 73-31-4

Molecular weight: 232.28 g/mol

Origin: Synthetic

Country of origin: China

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Easily soluble in alcohol. Slightly soluble in water.**5. PROPERTIES/USES**

Active pharmaceutical ingredient.

Active cosmetic ingredient.

As an active pharmaceutical ingredient:


Melatonin is a hormone produced from the amino acid tryptophan by the pineal gland. Melatonin is involved in the inhibition of gonadal development and the development of estrous. It also has a protective effect on skin colour changes.

The release of melatonin appears to occur in a daily rhythm. It is secreted at night and can affect sleep patterns. Due to its possible influence on circadian rhythm, melatonin has been found to relieve jet lag and other disorders resulting from sleep delays.

As an active cosmetic ingredient:

Used as an antioxidant.

In hair care products.

	GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.	
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	TECHNICAL DATA SHEET	
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6. DOSAGE

Orally as an active pharmaceutical ingredient:

- Management of short-term primary insomnia for patients over 55 years of age. Doses of 2 mg once daily administered 1 to 2 hours before bed and after eating, for 13 weeks.

Topical use as an active cosmetic ingredient:

- In hair care products at concentrations of 0.0033%.

7. REMARKS

STORAGE:

Store at room temperature (25±2°C), in a cool, dry place, away from sunlight, in a tightly closed container.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

The product does not contain or is derived from or manufactured using or coming into contact with raw materials of animal origin. Therefore, the product is considered BSE/TSE free.

GMOs:

The product has not been manufactured without using genetic modification techniques.

ALLERGENS:

The product does not contain ingredients derived from any allergenic material.

The product does not contain any of the substances listed in Annex II to Regulation 1169/2011, nor has it presented a risk of cross-contamination with the substances therein.

8. BIBLIOGRAPHY:

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993)."

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