FIRST TIME GENERIC APPROVAL

Brand Name	Hetlioz®
Generic Name	tasimelteon
Drug Manufacturer	Teva Pharmaceuticals, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

December 12, 2022

LAUNCH DATE

December 29, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 211601

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Tasimelteon is a melatonin receptor agonist. It is indicated for the treatment of non-24-hour sleep-wake disorder (non-24) in adults and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older.

MECHANISMS OF ACTION

Tasimelteon is an agonist at MT_1 and MT_2 receptors, which are believed to be involved in the promotion of sleep and the maintenance of the normal circadian rhythm (shift between day and night).

DOSE FORM AND STRENGTH

Capsules: 20 mg

DOSE & ADMINISTRATION

- Administer at the same time every night.
- Take with food.

RxAdvance

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Indicated Population	Dosage Form	Body Weight	Recommended Dosage
Non-24-hour sleep-wake disorder (non-24)			
Adult	Capsule	Not applicable	20 mg one hour prior to bedtime

Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)			
Age 16 years+	Capsule	Not applicable	20 mg one hour prior to bedtime