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2. Tasimelteon

Tasimelteon

Generic name: tasimelteon [TAS-i-MEL-tee-on]

Brand names: Hetlioz, Hetlioz LQ

Dosage forms: oral capsule (20 mg), oral suspension (4 mg/mL) **Drug class:** Miscellaneous anxiolytics, sedatives and hypnotics



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Uses Side effects Warnings Before taking Dosage Interactions

What is tasimelteon?

Tasimelteon is a sedative that is used to treat non-24-hour sleep-wake disorder in adults.

Tasimelteon is also used to treat nighttime sleep problems in people with a genetic disorder called Smith-Magenis Syndrome (SMS). The **capsule** form of tasimelteon is for people with SMS who are at least 16 years old. The **oral suspension (liquid)** form is for children with SMS who are from 3 to 15 years old.

Tasimelteon may also be used for purposes not listed in this medication guide.

Tasimelteon side effects

Get emergency medical help if you have **signs of an allergic reaction**: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have pain or burning when you urinate.

Side effects may be more likely in older adults.

Common side effects of tasimelteon may include:

- · headache;
- · abnormal liver function tests;
- strange dreams, nightmares; or
- · cold symptoms such as stuffy nose, sneezing, sore throat.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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Tasimelteon side effects (more detail)

Related/similar drugs

Hetlioz

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Warnings

Use only as directed. Tell your doctor if you use other medicines or have other medical conditions or allergies.

Before taking this medicine

Tell your doctor if you have ever had:

- liver disease; or
- if you smoke.

Tell your doctor if you are pregnant or breastfeeding.

Do not give tasimelteon to a child without medical advice. Tasimelteon is approved to treat nighttime sleep problems only in children who have SMS and are at least 3 years old. Tasimelteon is not approved to treat non-24-hour sleep-wake disorder in anyone younger than 18 years old.

How should I take tasimelteon?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed.

Take the medicine without food, 1 hour before your normal bedtime at the same time each night.

Read and follow all Instructions for Use. Ask your doctor or pharmacist if you need help. Do not allow a young child to use tasimelteon without help from an adult.

Swallow the capsule whole and do not crush, chew, break, or open it.

Tasimelteon **capsules** are for use in people 16 years and older. Tasimelteon **oral suspension** is for use only in children 3 to 15 years old.

Shake the **oral suspension** for at least 30 seconds before you measure a dose. Use the supplied syringe or a dose-measuring device (not a kitchen spoon). Do not remove the syringe adapter from the bottle neck. Recap the bottle and refrigerate after each use.

The capsules and liquid are not equivalent. Avoid medication errors by using only the form your doctor prescribes.

Doses are based on weight in children. Your child's dose may change if the child gains or loses weight.

You may not fully benefit from this medicine for several weeks or months.

Store capsules at room temperature away from moisture, heat, and light.

Store the **liquid** medicine in the refrigerator. Throw away any leftover liquid 5 weeks after opening the 48 mL bottle, or 8 weeks after opening the 158 mL bottle.

Tasimelteon dosing information

Usual Adult Dose for Insomnia:

20 mg orally once per day

Comments:

- -Take before bedtime, at the same time every night.
- -Take without food.

Use: Treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)

Detailed Tasimelteon dosage information

What happens if I miss a dose?

Skip the dose if you cannot take it at the regular time on a given night.

Do not use two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking tasimelteon?

After taking tasimelteon, avoid doing anything other than getting ready for bed.

What other drugs will affect tasimelteon?

Using tasimelteon with other drugs that make you drowsy can worsen this effect. Ask your doctor before using opioid medication, a sleeping pill, a muscle relaxer, or medicine for anxiety or seizures.

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Other drugs may affect tasimelteon, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all other medicines you use.

1 Tasimelteon drug interactions (more detail)

Does tasimelteon interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

tasimelteon
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Patient resources

Tasimelteon advanced reading

Other brands

Hetlioz, Hetlioz LQ

Professional resources

- Tasimelteon monograph
- Tasimelteon (FDA)

Other brands

Hetlioz

Related treatment guides

- Smith-Magenis Syndrome Sleep Disturbance
- Non-24-Hour Sleep Wake Disorder

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

ঝ্ Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

□ Drug history at FDA

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Tasimelteon 20 mg (A44)





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