

Announcing a NEW FDA APPROVAL for WAKIX

Wakix[®]
pitolisant tablets

WAKIX is NOW FDA APPROVED to treat excessive daytime sleepiness (EDS) in children 6 years of age and older with narcolepsy.

Why WAKIX?



Once-daily tablet taken in the morning



Not a controlled substance

WAKIX is the first and only FDA-approved treatment for people with narcolepsy that is **not a controlled substance**.



Not a stimulant

WAKIX is **not a stimulant**, so the way your child's body feels when taking WAKIX may be different from medications they have taken in the past.



First-of-its-kind

WAKIX is a **first-of-its-kind medication** that increases **histamine** levels in the brain.

Learn more about WAKIX at [WAKIX.com](https://www.wakix.com)

Indications and Usage

WAKIX is a prescription medicine used to treat:

- excessive daytime sleepiness (EDS) or cataplexy in adults with narcolepsy.
- excessive daytime sleepiness (EDS) in children 6 years of age and older with narcolepsy.

Important Safety Information

Do not take WAKIX if you are allergic to pitolisant or any ingredient in WAKIX, or if you have severe liver disease.

WAKIX can cause a change in the electrical activity of the heart known as QT prolongation. This is a heart rhythm problem that can lead to an abnormal heartbeat. You have a higher chance of getting QT prolongation if you have certain heart or other medical conditions, or if you take WAKIX with certain medicines. Tell your healthcare provider right away if you have a change in your heartbeat or if you feel dizzy or faint while taking WAKIX.

Tell your healthcare provider about all your medical conditions, including if you have any heart, liver, or kidney problems, or problems with blood levels of your electrolytes, such as potassium or magnesium.

Tell your healthcare provider about all the medicines you take or plan to take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking WAKIX with certain medicines may cause side effects or affect the way each other works.

Hormonal birth control methods may not work while taking WAKIX. Use an alternative non-hormonal birth control method during treatment with WAKIX and for at least 21 days after stopping WAKIX.

Tell your healthcare provider if you are pregnant or planning to become pregnant. You are encouraged to enroll in the WAKIX pregnancy registry if you become pregnant while taking WAKIX. The registry collects information about the health of you and your baby. To enroll or obtain information from the registry, call 1-800-833-7460.

The most common side effects of WAKIX in adults include insomnia, nausea, and anxiety.

The most common side effects of WAKIX in children include headache and insomnia.

These are not all the possible side effects of WAKIX. Call your healthcare provider for medical advice about side effects.

It is not known if WAKIX is safe and effective to treat excessive daytime sleepiness in children under 6 years of age with narcolepsy or to treat cataplexy in people under 18 years of age with narcolepsy.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. You can also report negative side effects to Harmony Biosciences at 1-800-833-7460.



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US-WAK-2400253/Jun 2024

Please see accompanying [Full Prescribing Information](#).