

Wakix[®]
pitolisant tablets

Is your child living with
NARCOLEPSY?

Wake Up
TO
WAKIX



**FDA approved to treat 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.

Please see Important Safety Information on pages 6-7
and accompanying [Full Prescribing Information](#).



Has Your Child Been Diagnosed With Narcolepsy?

From attending class to after-school activities, homework, and school projects, managing excessive daytime sleepiness (EDS) with narcolepsy can be challenging. If your child is having trouble staying awake during the day due to narcolepsy, **talk to their healthcare provider** about **WAKIX**.



Please see Important Safety Information on pages 6-7
and accompanying [Full Prescribing Information](#).

Why WAKIX?



Once-daily tablet taken in the morning

WAKIX is a **once-daily tablet medication taken in the morning** as soon as your child wakes up.



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.



Not a controlled substance

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



No significant drug interactions with sodium oxybate or modafinil

In a clinical study in adults where WAKIX was taken with sodium oxybate or modafinil, there were **no significant effects** on the levels of medications in the body.



First-of-its-kind

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

Important Safety Information

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.

WAKIX Significantly Reduced Excessive Daytime Sleepiness Compared With Placebo



WAKIX was studied for the treatment of excessive daytime sleepiness in a clinical trial of 110 patients (aged 6-17 years) with narcolepsy

- WAKIX was compared with placebo (sugar pill) using the Pediatric Daytime Sleepiness Scale (PDSS) questionnaire.
- This questionnaire uses an overall score to measure excessive daytime sleepiness by asking 8 questions about how often one falls asleep or gets drowsy during the day in situations such as:



Homework



Classroom

In this 8-week clinical trial:

- PDSS scores were evaluated for 72 patients treated with WAKIX, and 38 patients receiving placebo.
- 90 of the patients in the trial had narcolepsy with cataplexy, and 20 patients had narcolepsy without cataplexy.

At the end of the trial...



Scores on the PDSS were significantly improved for patients taking WAKIX compared with placebo

This means patients taking WAKIX reported falling asleep or getting drowsy less often during the day compared with patients who took placebo.

- Everyone responds to medication differently. Individual responses varied in the clinical trial.

What Side Effects Were Seen in the Clinical Trial?



In the clinical trial of patients aged 6-17 years with narcolepsy, the most common side effects of **WAKIX** that were greater than the rate of placebo (sugar pill) were headache and insomnia.

Side effects that occurred in at least 5% of patients treated with WAKIX and more frequently than placebo

	WAKIX (n=73)
Headache	19%
Insomnia	7%

n indicates the number of patients who were treated with WAKIX.



Overall, the side effects seen in the clinical trial of patients aged 6-17 years with narcolepsy were similar to those seen in adult clinical trials.

In the clinical trials of adults with narcolepsy:

- The most common side effects of WAKIX were insomnia, nausea, and anxiety.
- Other side effects of WAKIX included headache, upper respiratory tract infection, musculoskeletal pain, increased heart rate, hallucinations, irritability, abdominal pain, sleep disturbance, and decreased appetite.



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



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.



Important Safety Information (continued)

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.

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

Learn more about WAKIX at WAKIX.com

Information on Taking WAKIX



WAKIX tablets should be taken once daily in the morning, as soon as your child wakes up

WAKIX only needs to be taken once each day in the morning. Avoid taking WAKIX later in the day.

- If your child misses a dose, the next dose should be taken the following morning as soon as they wake up.
- WAKIX tablets should not be crushed or chewed.

Once-daily dosing

WAKIX should always be taken exactly as prescribed.

Take WAKIX

- ✓ In the morning, as soon as your child wakes up
- ✓ Once a day, every day
- ✓ With or without food

Do **NOT** take WAKIX

- ✗ Later in the day
- ✗ More than once a day
- ✗ Only on certain days

WAKIX comes in two tablet strengths (4.45 mg and 17.8 mg)



Getting Started With WAKIX



Your child's healthcare provider will work with you to find the dose that's right for them

- Depending on your child's weight and prescribed dose, they may have to take more than one tablet.
- Your child's healthcare provider will start them at a lower dose and increase the dose each week to find the right dose for them. This process is called **titration**.
 - Titration can take time, but it's important for your child's healthcare provider to find the dose that's right for them.
- WAKIX should always be taken exactly as prescribed.

Talk to a healthcare provider about all your child's medical conditions and the medicines your child takes or plans to take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



What Should I Expect When My Child Takes WAKIX?



When starting a medication, especially one for a chronic disorder like narcolepsy, it is important to talk to your child's healthcare provider so he or she can help you and your child understand what to expect with treatment.



WAKIX is *not* a stimulant

The way your child's body feels when taking WAKIX may be different from medications they have taken in the past.



It's important to give WAKIX time to work

Everyone responds to medication differently. It's important to know that WAKIX may take some time to work and for some people, it **may take up to 8 weeks to achieve a response.**

Discuss your child's progress with their healthcare provider



Talk with your child's healthcare provider about how they are feeling after starting WAKIX:

- Include any **improvements** you and your child notice as well as any **potential side effects**.
- **Don't stop or change the dose on your own** without talking to the healthcare provider first.
- The healthcare provider may be able to adjust the dose of WAKIX to find a dose that's right for them.

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

Notes



**Make a list of things you would like to discuss
with your child's healthcare provider**

The **WAKIX** for You Support Program Is Here to Help



Once your child's healthcare provider prescribes **WAKIX**, you can sign up for **WAKIX for You**, a program that provides individual financial support based on specific needs and eligibility.



Works with your insurance plan to determine coverage



Offers financial support programs for eligible patients



Ensures your child's prescription is sent to the Specialty Pharmacy so they can arrange delivery directly to you



Provides educational resources

\$0

You may be eligible to pay as little as a \$0 copay on your child's WAKIX prescription with the **WAKIX for You** Program.*

*This offer is valid only for patients who have commercial (nongovernment-funded) insurance. Additional terms and conditions apply.



Contact **WAKIX for You**



1-855-WAKIX4U
(1-855-925-4948)

Monday – Friday, 8 AM–8 PM, ET



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