

For adults living with
NARCOLEPSY...

Wake Up
TO
WAKIX

Wakix[®]
pitolisant tablets

Chris

Living with narcolepsy
Taking WAKIX since 2021

**FDA approved to treat excessive daytime sleepiness (EDS)
or cataplexy in adults 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 15–16 and accompanying [Full Prescribing Information](#).

Narcolepsy Shouldn't Stop You From Living Your Life

Living with narcolepsy is difficult, and finding ways to manage your excessive daytime sleepiness (EDS) or cataplexy can be a challenge.

You are not alone.

Living With Narcolepsy

The two most common symptoms of narcolepsy are excessive daytime sleepiness (EDS) and cataplexy



Everyone

with narcolepsy has **excessive daytime sleepiness**, the inability to stay awake and alert during the day or the persistent feeling of tiredness.



Nearly
2 out of 3

people with narcolepsy may also have **cataplexy**, the sudden onset of weak or paralyzed muscles, usually brought on by strong emotions or certain situations.



Approximately
170,000

people in the United States
are living with narcolepsy.

What Can EDS Feel Like?

People living with narcolepsy may experience their **excessive daytime sleepiness (EDS)** in different ways, like:



Fighting to stay awake

People may fight to stay awake throughout the day or fall asleep without warning.



Feeling sleepy soon after waking up

Some people may wake up feeling somewhat refreshed but feel sleepy again in a few hours.



Feeling sleepy in less active situations

People may feel sleepy in situations that require no active participation, such as watching TV or riding in a car.



Talk with your healthcare provider about your EDS and about how your EDS may be affecting you.

What Can Cataplexy Feel Like?

People living with narcolepsy who have **cataplexy** may experience it in different ways. Cataplexy can cause people with narcolepsy to collapse completely but more often occurs in specific areas of the body, like:



Knees buckling



Hand weakness
(dropping objects)



Jaw sagging

People may experience cataplexy in different ways, like:

- Muscle weakness or heaviness
- “Spells” of muscle weakness
- Slurred speech
- Drooping of the head, face, or eyelids
- Going slack-jawed
- Losing muscle control
- Clumsiness
- Loss of grip or dropping things



It's not always obvious to people that these experiences of cataplexy are related to narcolepsy.

Talk with your healthcare provider if you have experienced any of these signs of cataplexy, and how your cataplexy may be affecting you.



Wake Up TO WAKIX

Chris

Brother, friend, mental healthcare worker, living with narcolepsy
Taking WAKIX since 2021

Have you been diagnosed with narcolepsy?

Whether you're newly diagnosed with narcolepsy or have been diagnosed for years, **talk to your healthcare provider about how WAKIX** might help manage your excessive daytime sleepiness (EDS) or cataplexy.

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.



Hear Chris's story and other personal stories of how WAKIX has helped



FDA approved for adults with narcolepsy to treat:



**Excessive Daytime
Sleepiness (EDS)**



Cataplexy

**WAKIX can be taken to treat EDS, cataplexy, or both
in adults with narcolepsy.**

Why WAKIX[®] (pitolisant)?



First-of-its-kind

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



Once-daily tablet medication

WAKIX is a **once-daily tablet medication taken in the morning** as soon as you wake up.



Not a controlled substance

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

- In a clinical study in adults, WAKIX did not show potential for abuse, similar to placebo (sugar pill).



Not a stimulant

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

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.

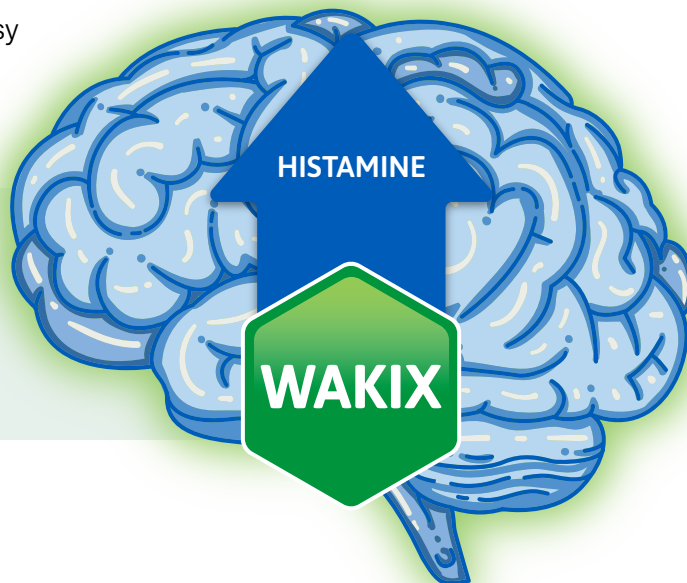


How Does WAKIX[®] (pitolisant) Work?

WAKIX is a first-of-its-kind medication that is thought to work differently

While the way WAKIX works is not fully understood, it is thought that WAKIX reduces **excessive daytime sleepiness (EDS)** or **cataplexy** in adults with narcolepsy by increasing histamine in the brain.

WAKIX increases histamine levels in the brain



Important Safety Information

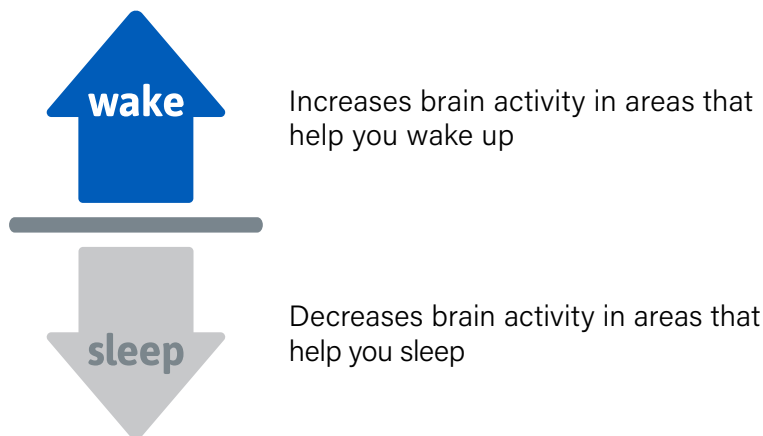
Tell your healthcare provider about all the medicines you take or plan to take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking WAKIX with certain medicines may cause side effects or affect the way each other works.

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What Does Histamine Do in the Brain?

Histamine is a natural chemical in the brain that works in two ways to help us stay awake during the day

Histamine:



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Watch a brief video at WAKIX.com

WAKIX® (pitolisant) Significantly Reduced EDS Compared With Placebo

WAKIX was studied for the treatment of **excessive daytime sleepiness (EDS)** in **two clinical trials** in **159 adult patients with narcolepsy**.

- WAKIX was compared with placebo (sugar pill) using a questionnaire called the Epworth Sleepiness Scale (ESS). The ESS measures the level of EDS by asking how likely you are to doze or fall asleep in 8 everyday situations.
- In the trials, 97 patients were treated with WAKIX, and 62 patients received placebo.

At the start of the trials, the majority of patients reported severe EDS

Their ESS scores were 16 or higher, which means they had a **high chance of dozing or falling asleep in everyday situations**, such as:



Reading



Watching TV



Sitting and talking

Trial 1 and Trial 2 were the clinical trials for EDS in adult patients with narcolepsy.

- Trial 1 was 8 weeks and included 61 adults with narcolepsy with or without cataplexy (31 patients were treated with WAKIX and 30 received placebo). About 80% of the patients in the trial had cataplexy and about 20% did not.
- Trial 2 was also 8 weeks and included 98 adults with narcolepsy with or without cataplexy (66 patients were treated with WAKIX and 32 received placebo). In this trial, 75% of patients had cataplexy and 25% did not.

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At the end of the trials...



ESS scores were significantly improved for patients taking WAKIX compared with placebo

This means patients taking WAKIX reported a **significantly lower ESS score, or lower chance of dozing or falling asleep in everyday situations** compared with placebo.

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



Hear Kristen's story at [WAKIX.com](https://www.wakix.com)



Significantly Fewer Cataplexy Attacks With WAKIX® (pitolisant) Compared With Placebo

WAKIX was studied for the treatment of **cataplexy** in **two clinical trials** in **154 adult patients with narcolepsy**.

- WAKIX was compared with placebo (sugar pill) by measuring how often patients in the trials experienced **cataplexy**. Cataplexy was defined as **sudden muscle weakness often triggered by emotions**.
- **One trial** measured the number of **weekly cataplexy attacks** and **the other trial** measured the number of **daily cataplexy attacks**.
- In the trials, 79 patients were treated with WAKIX, and 75 patients received placebo.

At the start of the trial measuring weekly cataplexy attacks, on average, patients had about 8 cataplexy attacks per week

Examples of cataplexy include:



Knees buckling



Hand weakness
(dropping objects)



Jaw sagging

Trial 3 and Trial 1 were the clinical trials for cataplexy in adult patients with narcolepsy.

- Trial 3 was 7 weeks and included 105 adults with narcolepsy with cataplexy (54 patients were treated with WAKIX and 51 received placebo). This trial measured the number of weekly cataplexy attacks.
- Trial 1 was 8 weeks and included 49 adults with narcolepsy with cataplexy (25 patients were treated with WAKIX and 24 received placebo). This trial measured the number of daily cataplexy attacks.

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At the end of this trial...



**Patients taking WAKIX
had about half as many
cataplexy attacks per week
compared with patients
taking placebo**

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



Hear Chris's story at [WAKIX.com](https://www.wakix.com)



Chris

Living with narcolepsy
Taking WAKIX since 2021



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.

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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.

Important Safety Information (continued)

Hormonal birth control methods may not work while taking WAKIX® (pitolisant). 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.

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



Learn more about WAKIX at WAKIX.com

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What Side Effects Were Seen in Clinical Trials?

In the clinical trials of adults with narcolepsy, the most common side effects of **WAKIX® (pitolisant)** and at least twice the rate of placebo (sugar pill) were:



Insomnia



Nausea



Anxiety

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

	WAKIX (n=152)	Placebo (n=114)
Headache	18%	15%
Insomnia	6%	2%
Nausea	6%	3%
Upper respiratory tract infection	5%	3%
Musculoskeletal pain	5%	3%
Anxiety	5%	1%

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

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Additional Information About Side Effects



Other side effects of **WAKIX® (pitolisant)** in the adult clinical trials included heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, and decreased appetite.



These are not all the possible side effects of WAKIX. Tell your healthcare provider about any side effect that bothers you or that does not go away.

In the adult clinical trials, some patients stopped treatment due to side effects. In these trials:

3.9%

of patients treated with
WAKIX stopped treatment
due to side effects

similar to

3.5%

of patients who received
placebo stopped treatment
due to side effects

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How Should I Take WAKIX[®] (pitolisant)?



WAKIX tablets should be taken once daily in the morning, as soon as you wake up

You only need to take WAKIX once each day in the morning. Avoid taking WAKIX later in the day.

- If you miss a dose, take the next dose the following morning as soon as you wake up.

WAKIX comes in two tablet strengths (4.45 mg & 17.8 mg). Depending on your dose, you may have to take more than one tablet.

TAKE WAKIX

- ✓ In the morning, as soon as you wake 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

If you have any questions about when to take WAKIX, talk with your healthcare provider.



Always take WAKIX exactly as your healthcare provider has prescribed.

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How Will I Get Started on WAKIX® (pitolisant)?



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

Your healthcare provider will start at a lower dose and increase your dose each week to find the right dose for you. This process is called **titration**.

- Titration can take time, but it's important for you and your healthcare provider to find the dose that's right for you.

Talk to your healthcare provider about how you are feeling after starting WAKIX.

- Tell them about any **improvements** you notice as well as **any potential side effects**.



Do not stop or change the dose on your own without talking to your healthcare provider first. If you have any questions, talk with your healthcare provider.

“My doctor and I had open communication about everything as we focused on getting to the right dose for me.”

~ Kristen



Can I Take Antihistamines if I'm Taking WAKIX® (pitolisant)?



Some kinds of antihistamines should be avoided with WAKIX

Certain antihistamines can prevent histamine from working in the brain. These medications may reduce the effectiveness of WAKIX and should be avoided.



Ask your healthcare provider about medications that can be taken with WAKIX

Your healthcare provider may be able to provide suggestions about what antihistamines or alternative treatments can be taken with WAKIX and which antihistamines should be avoided.

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.



What Else Should I Know About WAKIX® (pitolisant)?



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 the medications in the body.

- Tell your healthcare provider about all the medicines you take or plan to take.



May reduce effectiveness of hormonal contraceptives

Hormonal birth control methods may not work while taking WAKIX.

- People who can become pregnant should use an alternative non-hormonal birth control method during treatment with WAKIX and for at least 21 days after stopping WAKIX.



Not a controlled substance

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

- A controlled substance is a drug or chemical that is regulated by the government based on its potential for abuse and dependence.
- In a clinical study in adults, WAKIX did not show potential for abuse, similar to placebo (sugar pill).

Important Safety Information

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.



What Should I Expect When I Take WAKIX® (pitolisant)?

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

Here are a few things to discuss with your healthcare provider about what to expect with WAKIX:



WAKIX is **not** a stimulant

The way your body feels when taking WAKIX may be different from medications you 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 progress with your healthcare provider

Talk about how you are feeling after starting WAKIX:

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





Individual responses to WAKIX may vary.

"A few weeks after I titrated up to the right dose for me, I noticed incremental shifts in my overall wakefulness and a decrease in my sleepiness."

Kristen

Living with narcolepsy
Taking WAKIX since 2020

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Hear Kristen's story and other personal stories at [WAKIX.com](https://www.wakix.com)

Hear What Real People Have to Say About WAKIX



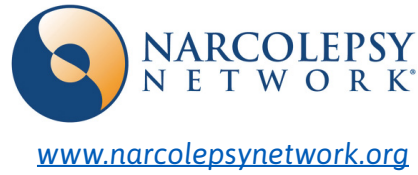
Watch real people living with narcolepsy as they share their journeys
with the disorder and how WAKIX has helped them



Hear more personal stories at [WAKIX.com](https://www.wakix.com)

Find Support Groups and Learn More

There are several groups and organizations that can provide information, support, and more for people living with narcolepsy and their loved ones.



[Learn more](#) about finding support in the narcolepsy community



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

Once your healthcare provider prescribes **WAKIX® (pitolisant)**, you have the option to sign up for **WAKIX for You**, a program that provides individual reimbursement and financial support based on your specific needs and eligibility.



Works with your insurance plan to determine coverage



Offers financial support programs for eligible patients



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



Provides educational resources

Wakix
for You™

Contact **WAKIX for You**



1-855-WAKIX4U

(1-855-925-4948)

Monday–Friday, 8 AM–8 PM ET

\$0

You may be eligible to pay as little as a \$0 copay on your 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.



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Harmony Biosciences name and logo are registered trademarks.
All other trademarks are the property of their respective owners.
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US-WAK-2400463/Aug 2024

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