

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.

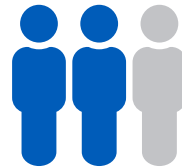
Living With Narcolepsy

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
165,000

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.

Wakix[®]
pitolisant tablets

Wake Up
TO
WAKIX

Chris

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

Whether you're newly diagnosed with narcolepsy or have been diagnosed for years and are ready for a change, **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 sudden onset of weak or paralyzed muscles (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.



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



FDA approved 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 the first and only **once-daily tablet medication** that is **FDA approved** to treat excessive daytime sleepiness (EDS) or cataplexy in adults with narcolepsy.



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, 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

Tell your healthcare provider about all your medical conditions, including if you have heart rhythm irregularities, were born with a heart condition, or the levels of electrolytes in your blood are too high or too low. WAKIX has an effect on the electrical activity of the heart known as QT prolongation. Medicines with this effect can lead to disturbances in heart rhythm, which are more likely in patients with risk factors such as certain heart conditions, or when taken in combination with other medicines that affect QT. Tell your healthcare provider about all the other medicines you take.

The risk of QT prolongation may be greater in patients with liver or kidney disease. WAKIX is not recommended in patients with end-stage kidney disease.

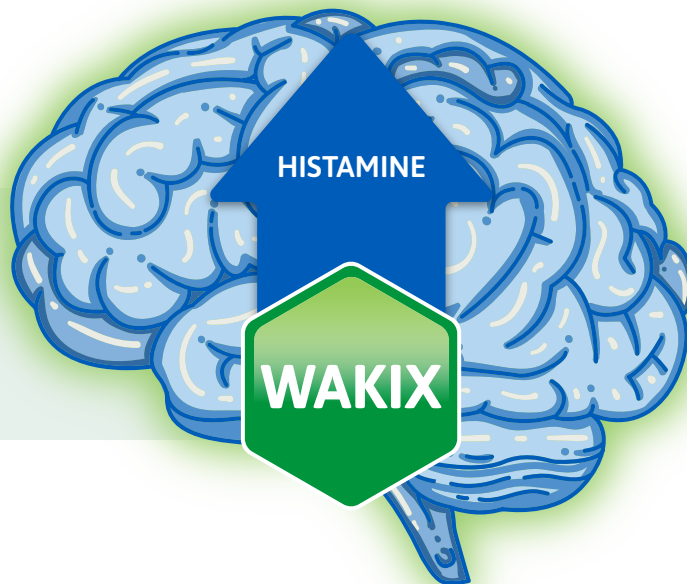


How Does WAKIX[®] (pitolisant) Work?

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** by increasing histamine in the brain.

WAKIX increases histamine levels in the brain



Important Safety Information

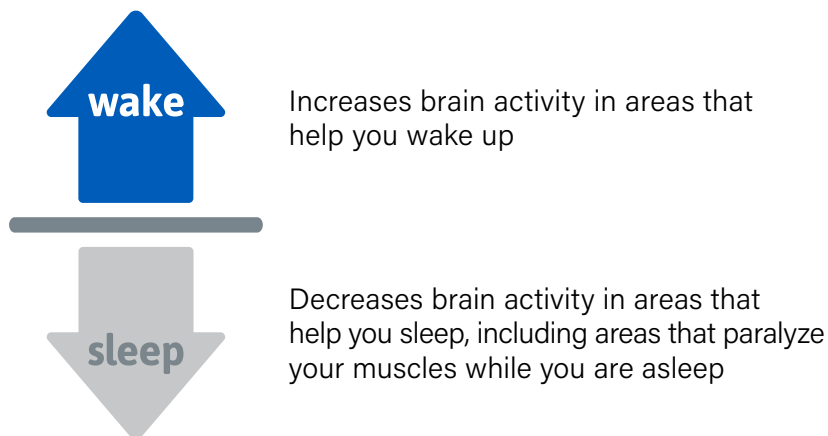
Tell your healthcare provider about all the medicines you take or plan to take, including **prescription and over-the-counter medicines**. Some medicines can increase the amount of WAKIX that gets into your blood and some medicines can decrease the amount of WAKIX that gets into your blood. The dosage of WAKIX may need to be adjusted if you are taking these medicines.

Wakix[®]
pitolisant tablets

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:



Wakix[®]
pitolisant tablets



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 adults 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.

- 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.

Wakix[®]
pitolisant tablets



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)



Kristen

Living with narcolepsy
Taking WAKIX since 2020

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

WAKIX was studied for the treatment of **cataplexy** in **two clinical trials** in **154 adults 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.

- 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.

Wakix[®]
pitolisant tablets



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 sudden onset of weak or paralyzed muscles (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.

Tell your healthcare provider about all your medical conditions, including if you have heart rhythm irregularities, were born with a heart condition, or the levels of electrolytes in your blood are too high or too low. WAKIX has an effect on the electrical activity of the heart known as QT prolongation. Medicines with this effect can lead to disturbances in heart rhythm, which are more likely in patients with risk factors such as certain heart conditions, or when taken in combination with other medicines that affect QT. Tell your healthcare provider about all the other medicines you take.

The risk of QT prolongation may be greater in patients with liver or kidney disease. WAKIX is not recommended in patients with end-stage kidney disease.

The most common side effects seen with WAKIX were insomnia, nausea, and anxiety. Other side effects included headache, upper respiratory tract infection, musculoskeletal pain, heart rate increased, 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.

Important Safety Information (continued)

Tell your healthcare provider about all the medicines you take or plan to take, including prescription and over-the-counter medicines. Some medicines can increase the amount of WAKIX® (pitolisant) that gets into your blood and some medicines can decrease the amount of WAKIX that gets into your blood. The dosage of WAKIX may need to be adjusted if you are taking these medicines.

WAKIX can also decrease the effectiveness of some medicines, including hormonal birth control methods. You should use an alternative non-hormonal birth control method during treatment with WAKIX and for at least 21 days after discontinuation of treatment.

Tell your healthcare provider if you are pregnant or planning to become pregnant. There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to WAKIX during pregnancy. You are encouraged to enroll in the WAKIX pregnancy registry if you become pregnant while taking WAKIX. To enroll or obtain information from the registry, call 1-800-833-7460.

The safety and effectiveness of WAKIX have not been established in patients less than 18 years of age.

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.



Learn more about WAKIX at WAKIX.com

Wakix[®]
pitolisant tablets

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.



Additional Information About Side Effects



Other side effects of **WAKIX® (pitolisant)** in the 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 clinical trials, some patients stopped treatment due to side effects. In these trials:



Wakix[®]
pitolisant tablets

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. **Always take WAKIX exactly as your healthcare provider has prescribed.**

TAKE WAKIX

- ✓ In the morning, as soon as you wake up
- ✓ Once a day
- ✓ Every day

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.

Important Safety Information

Tell your healthcare provider about all the medicines you take or plan to take, including prescription and over-the-counter medicines. Some medicines can increase the amount of WAKIX that gets into your blood and some medicines can decrease the amount of WAKIX that gets into your blood. The dosage of WAKIX may need to be adjusted if you are taking these medicines.



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

Wakix[®]
pitolisant tablets

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.



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



No significant drug interactions with sodium oxybate or modafinil

In a clinical study 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

WAKIX may reduce the effectiveness of **hormonal contraceptives (birth control)**.

- Women who can become pregnant should use an alternative non-hormonal type of birth control while taking WAKIX and for at least 21 days after discontinuation of treatment.



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, 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.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to WAKIX during pregnancy. You are encouraged to enroll in the WAKIX pregnancy registry if you become pregnant while taking WAKIX. 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 doctor may be able to adjust your dose of WAKIX to find a dose that is right for you.

Wakix[®]
pitolisant tablets



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

Wakix[®]
pitolisant tablets



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.



WAKIX is a registered trademark and WAKIX for You is a trademark of Bioprojet Europe, Ltd.
Harmony Biosciences name and logo are registered trademarks.
© 2023 Harmony Biosciences. All rights reserved.
US-WAK-2200260/Feb 2023

Wakix
pitolisant tablets