



Set Your Patients' Expectations About WAKIX

Key points to discuss with your patients about dosing and response to treatment

Indications and Usage

- WAKIX is indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy.

Important Safety Information

Contraindications

- WAKIX is contraindicated in patients with known hypersensitivity to pitolisant or any component of the formulation. Anaphylaxis has been reported. WAKIX is also contraindicated in patients with severe hepatic impairment.

Warnings and Precautions

- WAKIX prolongs the QT interval; avoid use of WAKIX in patients with known QT prolongation or in combination with other drugs known to prolong the QT interval. Avoid use in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval.
- The risk of QT prolongation may be greater in patients with hepatic or renal impairment due to higher concentrations of pitolisant; monitor these patients for increased QTc. Dosage modification is recommended in patients with moderate hepatic impairment and moderate or severe renal impairment (see full prescribing information). WAKIX is not recommended in patients with end-stage renal disease (ESRD).

Access more WAKIX tools and resources at [WAKIXhcp.com/resource-center](https://www.wakixhcp.com/resource-center)

Before Patients Start WAKIX



Help them understand WAKIX dosing and set expectations about clinical response

Introduce WAKIX

- Explain that WAKIX is not a stimulant or a controlled substance

Describe dosing and titration

- Tell your patients WAKIX should be taken once daily in the morning, as soon as they wake up
- Spend time discussing the titration process and share that they will start at a lower dose of WAKIX, and that you may increase the dose each week for 2-3 weeks to find the right dose for them. Remind them to always take WAKIX exactly as prescribed

Discuss expected response to treatment

- Share that everyone responds to medication differently. Symptoms may improve at different times or rates when taking WAKIX and it may take up to 8 weeks for some patients to achieve a clinical response
 - Recommend that they keep a journal for the first few months after starting WAKIX to track any improvements they are noticing
 - Suggest identifying a few activities to use as benchmarks throughout treatment
- Review side effect profile and note that the most common side effects observed in clinical studies for WAKIX compared with placebo were insomnia, nausea, and anxiety
 - Remind them to let you know of any medication changes or if they experience side effects



Encourage your patients to sign up for the *WAKIX for You* patient support program

- Patients can call **1-855-WAKIX4U** (1-855-925-4948) with questions or concerns

Important Safety Information

Adverse Reactions

- In the placebo-controlled clinical trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions ($\geq 5\%$ and twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at $\geq 2\%$ and more frequently than in patients treated with placebo included headache, upper respiratory infection, musculoskeletal pain, heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash.

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After Patients Start WAKIX



Check in with your patients during titration and their first few weeks on WAKIX to help them stay on track

Revisit appropriate dosing and the titration process

- Confirm that they are taking WAKIX as prescribed: once daily in the morning as soon as they wake up
- Reiterate that the titration process can take a few weeks, but it's important to find the dose that's right for them
- Let them know you may be able to adjust their dose of WAKIX to find a dose that's right for them

Review expected response to treatment

- Remind them that symptoms may improve at different times or rates when taking WAKIX and that it may take up to 8 weeks for some patients to achieve a clinical response
- Inquire about any improvements they have noticed as well as any potential side effects
- Ask if there are activities they can do now, that they were unable to do before because of their EDS or cataplexy
 - Assess benchmark activities identified prior to initiating treatment



Encourage your patients to hear from real people taking WAKIX at [WAKIX.com/wakix-personal-stories](https://www.wakix.com/wakix-personal-stories)

Important Safety Information

Drug Interactions

- Concomitant administration of WAKIX with strong CYP2D6 inhibitors increases pitolisant exposure by 2.2-fold. Reduce the dose of WAKIX by half.
- Concomitant use of WAKIX with strong CYP3A4 inducers decreases exposure of pitolisant by 50%. Dosage adjustments may be required (see full prescribing information).
- H₁ receptor antagonists that cross the blood-brain barrier may reduce the effectiveness of WAKIX. Patients should avoid centrally acting H₁ receptor antagonists.
- WAKIX is a borderline/weak inducer of CYP3A4. Therefore, reduced effectiveness of sensitive CYP3A4 substrates may occur when used concomitantly with WAKIX. The effectiveness of hormonal contraceptives may be reduced when used with WAKIX and effectiveness may be reduced for 21 days after discontinuation of therapy.

Access more WAKIX tools and resources at [WAKIXhcp.com/resource-center](https://www.wakixhcp.com/resource-center)

Helping Your Patients Meet Their Treatment Goals



Provide support for your patients throughout their treatment with WAKIX

Ensure WAKIX is taken appropriately and at a tolerable dose

- Ask if they have been taking WAKIX once daily in the morning as soon as they wake up
- Let them know you may be able to adjust their dose of WAKIX to find a dose that's right for them

Encourage patience for the first several weeks

- Share that it is important to give WAKIX a chance to work
 - It may take up to 8 weeks for some patients to achieve a clinical response
- Tell them that it can sometimes be hard to recognize a response to treatment
 - To help patients understand their progress, ask if there are activities they can do now, that they were unable to do before because of their EDS or cataplexy
 - Ask about progress with their benchmark activities to help them understand how treatment may have helped
 - If a close friend or family member is with the patient, ask if they have noticed any improvements in symptoms

Important Safety Information

Use in Specific Populations

- WAKIX may reduce the effectiveness of hormonal contraceptives. Patients using hormonal contraception should be advised to use an alternative non-hormonal contraceptive method during treatment with WAKIX and for at least 21 days after discontinuing treatment.
- There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to WAKIX during pregnancy. Patients should be encouraged to enroll in the WAKIX pregnancy registry if they become pregnant. To enroll or obtain information from the registry, patients can call 1-800-833-7460.
- The safety and effectiveness of WAKIX have not been established in patients less than 18 years of age.
- WAKIX is extensively metabolized by the liver. WAKIX is contraindicated in patients with severe hepatic impairment. Dosage adjustment is required in patients with moderate hepatic impairment.
- WAKIX is not recommended in patients with end-stage renal disease. Dosage adjustment of WAKIX is recommended in patients with moderate or severe renal impairment.
- Dosage reduction is recommended in patients known to be poor CYP2D6 metabolizers; these patients have higher concentrations of WAKIX than normal CYP2D6 metabolizers.

To report suspected adverse reactions, contact Harmony Biosciences at 1-800-833-7460 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



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