Wakix®
pitolisant tablets

Frequently Asked Questions About WAKIX

Understanding more about WAKIX

Q. How is WAKIX thought to work?

A. The mechanism of action of WAKIX in excessive daytime sleepiness or cataplexy in adult patients with narcolepsy is unclear; however, its efficacy could be mediated through its activity at histamine 3 (H_3) receptors, which results in increased levels of histamine in the brain.

Watch this video to understand how WAKIX is thought to work.

Q. What symptoms of narcolepsy does WAKIX treat?

A. WAKIX is indicated for the treatment of EDS or cataplexy in adult patients with narcolepsy.

Q. Do patients have to have both EDS and cataplexy to take WAKIX?

A. No, patients do not have to have both EDS and cataplexy to take WAKIX.

Q. Is WAKIX a stimulant?

A. No, WAKIX is not a stimulant.

Q. Is WAKIX a controlled substance?

A. No, WAKIX is not a controlled substance; it is the first and only FDA-approved non-scheduled treatment for EDS or cataplexy in narcolepsy.

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.

Learn more about WAKIX at **WAKIXhcp.com**

Please see Important Safety Information continued on next page and accompanying Full Prescribing Information.

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Considering WAKIX for your patient

Q. Is there a pregnancy exposure registry for WAKIX?

A. 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 visit WakixPregnancyRegistry.com or call the WAKIX Pregnancy Registry Coordination Center at **1-877-302-2813**.

Q. Can WAKIX be taken with hormonal contraceptives?

A. The effectiveness of hormonal contraceptives may be reduced when used with WAKIX and effectiveness may be reduced for 21 days after discontinuation of treatment. Advise patients to use an alternative non-hormonal contraceptive method during treatment with WAKIX and for at least 21 days after discontinuation of treatment.

Q. Is a baseline electrocardiogram (ECG) required prior to starting treatment with WAKIX?

A. The Prescribing Information for WAKIX does not have a requirement for a baseline ECG prior to starting WAKIX. WAKIX increases the QT interval; the highest recommended dose (35.6 mg) led to a QTc increase of 4.2 msec. Exposures that were 3.8-fold higher than achieved at the highest recommended dose led to a QTc increase of 16 msec (mean). Avoid use of WAKIX in patients with known QT prolongation; in patients with a history of cardiac arrhythmias or other risk factors for QT interval prolongation; or in combination with other drugs known to prolong the QT interval. Monitor patients with hepatic or renal impairment for increased QTc. See Full Prescribing Information for more information.

Q. What are common adverse reactions with WAKIX?

A. In the placebo-controlled clinical studies conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions (occurring in ≥5% of patients and at least twice the rate of placebo) with the use of WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Additional adverse reactions occurring in ≥2% of WAKIX-treated patients and more frequently than in placebo-treated patients were headache, upper respiratory tract infection, musculoskeletal pain, heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash.

View the safety profile of WAKIX in clinical studies.

Important Safety Information

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).

Learn more about WAKIX at **WAKIXhcp.com**

Please see Important Safety Information continued on next page and accompanying Full Prescribing Information.

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Dosing and titrating WAKIX

Q. How should WAKIX be taken?

A. WAKIX should be taken once daily in the morning upon wakening and is titrated to the recommended dose range of 17.8 mg to 35.6 mg. See questions below and Full Prescribing Information.

After initiating treatment with WAKIX, it's important to regularly assess patients for symptom improvement and tolerability. The dose of WAKIX may be adjusted based on tolerability.

View the recommended dosing and titration for WAKIX.

Q. What is the recommended titration for WAKIX?

A. Initiate at 8.9 mg (two 4.45-mg tablets) once daily for Week 1, increase to 17.8 mg (one 17.8-mg tablet) once daily for Week 2, and may increase to maximum recommended dosage of 35.6 mg (two 17.8-mg tablets) once daily for Week 3. Dosing modifications are recommended for some patients. See question below and Full Prescribing Information.

Watch this video to understand WAKIX dosing and titration.

Q. Are there any dosing modifications for WAKIX?

A. Yes, dosing modifications are recommended for patients with moderate hepatic impairment, patients with moderate or severe renal impairment, patients known to be poor CYP2D6 metabolizers, and patients receiving concomitant strong CYP2D6 inhibitors or strong CYP3A4 inducers. See Full Prescribing Information for recommended dosage and titration.

Use this tool to identify drug interactions and recommendations for dosing WAKIX with other medications.

Q. Are there any PK interactions with WAKIX and other narcolepsy medications?

A. In a clinical pharmacokinetics (PK) study to evaluate the concomitant use of WAKIX with modafinil or sodium oxybate, WAKIX had no effect on the PK of modafinil or sodium oxybate, and these agents had no clinically relevant effect on the PK of WAKIX.

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).
- H_1 receptor antagonists that cross the blood-brain barrier may reduce the effectiveness of WAKIX. Patients should avoid centrally acting H_1 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.

Learn more about WAKIX at **WAKIXhcp.com**

Please see Important Safety Information continued on next page and accompanying Full Prescribing Information.

Setting your patients' expectations about WAKIX® (pitolisant)

Q. What are some important things to discuss with patients when initiating treatment with WAKIX?

A. Before your patient begins treatment with WAKIX:

- Explain that WAKIX should be taken once daily, not on an as-needed basis. WAKIX is to be taken in the morning as soon as they wake up.
- Clarify that WAKIX will be titrated to the effective dosage.
- Treatments work differently; remind patients that WAKIX may take time to work; explain that WAKIX is not a stimulant.
- Advise about possible side effects and dosage modifications if taking WAKIX with other medications.

Share this brochure with your patients so they can learn more about WAKIX.

Q. When can patients expect to see a clinical response with WAKIX?

A. Symptoms may improve at different times or rates when taking WAKIX; it may take up to 8 weeks for some patients to achieve a clinical response.

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 **1-877-302-2813**.
- 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.

Learn more about WAKIX at **WAKIXhcp.com**

HARMONY BIOSCIENCES

Wakix® pitolisant tablets

Please see accompanying Full Prescribing Information.