Convenient Once-Daily Dosing

Wakix® pitolisant tablets

The recommended dosage range for WAKIX for the treatment of EDS or cataplexy in adult patients is 17.8 mg to 35.6 mg taken once daily in the morning upon wakening

- WAKIX is available in two tablet strengths for titration and flexible dosing: 4.45 mg and 17.8 mg

Individually Titrate WAKIX to the Effective Dosage*

	WEEK 1	**Initiate at 8.9 mg** Two 4.45-mg tablets once daily
	WEEK 2	**Increase to 17.8 mg** One 17.8-mg tablet once daily
Maximum Recommended Dosage	WEEK 3	**May increase to 35.6 mg** Two 17.8-mg tablets once daily

*Recommended titration schedule. Not all patients respond equally to WAKIX.

- After initiating treatment with WAKIX, it is important to regularly assess patients for symptom improvement and tolerability
  - Dose may be adjusted based on tolerability

Dosage modifications

- Dosage modifications are recommended for patients with moderate hepatic impairment, patients with moderate or severe renal impairment, patients receiving concomitant strong CYP2D6 inhibitors or strong CYP3A4 inducers, and patients known to be poor CYP2D6 metabolizers; see Full Prescribing Information for recommended dosage and titration

WAKIX had no clinically important pharmacokinetic (PK) interactions with modafinil or sodium oxybate

- In a clinical PK study in adults, 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[1]

Access an interactive tool to identify drug interactions and recommendations for dosing WAKIX with other medications at WAKIXhcp.com

Indications and Usage

- WAKIX is indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy and for the treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older 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. WAKIX is contraindicated in patients with severe hepatic impairment and not recommended in patients with end-stage renal disease (ESRD).

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

Setting Appropriate Patient Expectations

Wakix® pitolisant tablets

WAKIX is not a controlled substance

WAKIX should be taken once daily in the morning upon wakening

It may take up to 8 weeks for some patients to achieve a clinical response

WAKIX is not a stimulant

Visit WAKIXhcp.com for resources, real patient cases, and to download the WAKIX Prescription Referral Form

Important Safety Information

Adverse Reactions

- In the placebo-controlled clinical trials conducted in adult patients with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and at least twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at ≥2% and more frequently than in patients treated with placebo included headache, upper respiratory tract infection, musculoskeletal pain, heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash.
- In the placebo-controlled phase of the clinical trial conducted in pediatric patients 6 years and older with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and greater than placebo) for WAKIX were headache (19%) and insomnia (7%). The overall adverse reaction profile of WAKIX in the pediatric clinical trial was similar to that seen in the adult clinical trial program.

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.
- 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. WAKIX may reduce the effectiveness of sensitive CYP3A4 substrates, including 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.

Use in Specific Populations

- 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 for the treatment of excessive daytime sleepiness in pediatric patients less than 6 years of age with narcolepsy. The safety and effectiveness of WAKIX have not been established for the treatment of cataplexy in pediatric patients with narcolepsy.
- WAKIX is extensively metabolized by the liver. WAKIX is contraindicated in patients with severe hepatic impairment. Dosage adjustment is recommended 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 eGFR <60 mL/minute/1.73 m^2.
- 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.

Reference: 1. Data on file. Harmony Biosciences.

HARMONY BIOSCIENCES

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