



Kayce

Age: 12

Hobby:
Drawing

Diagnosis:
Narcolepsy without
cataplexy (narcolepsy type 2;
newly diagnosed)

Reason for visit:
• Ongoing EDS

Ongoing Symptoms

- Reports ongoing EDS

Clinical History

- ADHD
- Mild intellectual disability
- Patient's weight: 51 kg (113 lb)

Diagnostic Testing

- Narcolepsy without cataplexy (narcolepsy type 2; newly diagnosed)
 - SOREMP on nocturnal PSG
 - No evidence of other primary sleep disorders on PSG or during clinical interview

Smoking/Drug/Alcohol Use

- Does not use tobacco, drugs, or alcohol

Current Medications

- Stimulant for ADHD

Treatment Decision

- Started WAKIX to treat ongoing EDS in narcolepsy

ADHD, attention-deficit/hypersensitivity disorder; EDS, excessive daytime sleepiness; PSG, polysomnogram; SOREMP, sleep-onset REM period.

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

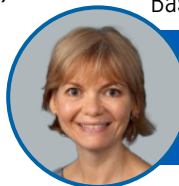
Contraindications

- 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).

Based on an actual patient case provided by:



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Wakix
pitolisant tablets

KayceMiddle school
student**Why WAKIX?**

- Established efficacy and safety in adult and pediatric clinical studies in narcolepsy
- Convenient once-daily morning dosing
- First and only histaminergic treatment for excessive daytime sleepiness (EDS) in pediatric patients (6 years and older) with narcolepsy and for EDS or cataplexy in adult patients with narcolepsy
- Not a controlled substance

WAKIX Titration and Administration

- WAKIX was initiated at a dosage of 4.45 mg once daily and titrated weekly to a dosage of 35.6 mg once daily (maximum recommended dosage for pediatric patients ≥ 6 years and ≥ 40 kg) by Week 4
 - Administered once daily in the morning upon waking

Clinical Outcome

- At 3-month follow-up, HCP's assessment of ongoing symptoms showed a reduction in EDS

Not all patients respond equally to WAKIX. Individual results may vary.

Setting Patient and Caregiver Expectations

When WAKIX was initiated, Kayce and his parents were advised:



WAKIX is not a stimulant



WAKIX is not a controlled substance



WAKIX should be taken once daily in the morning upon waking



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



After initiating treatment with WAKIX, it's important to regularly assess patients for symptom improvement and tolerability

EDS, excessive daytime sleepiness.

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 ($\geq 5\%$ and at least 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 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 ($\geq 5\%$ 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.

Wakix
pitolisant tablets

For pediatric patients with narcolepsy, like Kayce:



Why WAKIX?



Established efficacy and safety in adult and pediatric clinical studies in narcolepsy



Convenient once-daily morning dosing



First and only histaminergic treatment for excessive daytime sleepiness (EDS) in pediatric patients (6 years and older) with narcolepsy and for EDS or cataplexy in adult patients with narcolepsy



Not a controlled substance

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.
- 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. 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 m².
- 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.

Visit WAKIXhcp.com to view more WAKIX patient case studies



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US-WAK-2500010/Apr 2025

