Wakix® pitolisant tablets

Based on an actual patient case provided by:

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Emma

Age: 17
Hobby: Playing field hockey
Diagnosis: Narcolepsy with cataplexy (narcolepsy type 1; diagnosed 1 year ago)
Reason for visit: Ongoing EDS

WAKIX Patient Case Series

Ongoing Symptoms

- Reports ongoing EDS
  - Patient diagnosed with narcolepsy type 1 at 16 years of age; shows continued signs of EDS
- Reports cataplexy, typically triggered by laughter

Clinical History

- Narcolepsy with cataplexy (narcolepsy type 1; diagnosed 1 year ago)*
  - Mean sleep latency 2.9 minutes and 1 SOREMP on MSLT
  - No evidence of other primary sleep disorders on PSG or during clinical interview
- ADHD
- Migraine
- Anxiety
- Patient's weight: 54 kg (119 lb)

Current Medications

- Stimulant for ADHD
- Sodium oxybate for EDS and cataplexy

*Narcolepsy diagnosis based on DSM-5-TR criteria.
ADHD, attention-deficit/hyperactivity disorder; DSM-5-TR, *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition, text revision; EDS, excessive daytime sleepiness; MSLT, Multiple Sleep Latency Test; PSG, polysomnogram; SOREMP, sleep-onset REM period.

Indications and Usage

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

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Emma

17-year-old high school student

Why WAKIX?

- Demonstrated efficacy and safety in clinical studies in adult and pediatric patients (6 years and older) with narcolepsy type 1 and narcolepsy type 2
- Not a controlled substance
- First-in-class histaminergic treatment for patients with narcolepsy with or without cataplexy
- Once-daily morning dosing

WAKIX Patient Case Series

Treatment Decision

- Added WAKIX to treat ongoing EDS and cataplexy in narcolepsy
  - No other changes made to current narcolepsy treatment regimen

WAKIX Titration and Administration

- WAKIX was initiated at a dosage of 4.45 mg once daily and titrated weekly to a dosage of 17.8 mg once daily by Week 3
  - Administered once daily in the morning upon wakening

Clinical Outcome

- At 8-week follow-up, HCP's assessment of ongoing symptoms showed a reduction in EDS and cataplexy

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

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

EDS, excessive daytime sleepiness.

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 higher concentrations of pitolisant (e.g., patients with hepatic or renal impairment). Monitor patients with hepatic or renal impairment 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).

Setting Patient and Caregiver Expectations

When WAKIX was initiated, Emma and her parents were advised:

- WAKIX is not a stimulant
- 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® pitolisant tablets

Michael Strunc, MD

Visit WAKIXhcp.com to view more WAKIX patient case studies

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.

Wakix pitolisant tablets | RX CENTER for Healthcare Professionals

Visit the WAKIX RxCenter to...

- **Complete the WAKIX Prescription Referral Form**
- **Check formulary coverage**
- **Access prior authorization resources**
- **Find Specialty Pharmacy contact information**

Visit **WAKIXRxCenter.com** to download the WAKIX Prescription Referral Form

Important Safety Information

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 or cataplexy in pediatric patients less than 6 years of age 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.
- The maximum recommended dosage is lower in patients who are CYP2D6 poor metabolizers because these patients have higher pitolisant concentrations than CYP2D6 normal metabolizers and may have increased risk of adverse events.

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.

HARMONY BIOSCIENCES

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