Abby

Age: 24

Occupation:
Computer programmer

Initial diagnosis:
Narcolepsy without cataplexy (narcolepsy type 2; diagnosed 2 years ago)

Reason for visit:
Routine 3-month visit

- *Ongoing EDS*

Ongoing Symptoms

- Despite treatment to manage her EDS, ongoing symptoms still significantly interfere with daily activities
  - Often leaves class to splash water on her face to help stay awake
- Describes EDS as "constant fatigue"
  - ESS score of 18
- Repeated thoughtful questioning reveals recent onset of cataplexy
  - Describes feeling like her face was "melting," and "tingling" in her knees during excitement; no history of complete collapse
  - Muscle weakness not apparent to family members

Clinical History

- Narcolepsy without cataplexy (narcolepsy type 2; diagnosed 2 years ago)
  - Mean sleep latency 2.5 min and 4 SOREMPs on MSLT
  - No evidence of other primary sleep disorders on PSG or during clinical interview
  - ESS score of 22 at diagnosis
  - Cataplexy was not reported during clinical interview at initial diagnosis

Current Medications

- Modafinil and sodium oxybate for EDS in narcolepsy

Diagnosis

- Clinical interview reveals narcolepsy type 1 (diagnosis revised due to onset of cataplexy)

Treatment Decision

- Added WAKIX to treat ongoing EDS and cataplexy in narcolepsy

EDS, excessive daytime sleepiness; ESS, Epworth Sleepiness Scale; MSLT, Multiple Sleep Latency Test; PSG, polysomnogram; SOREMP, sleep-onset REM period.
Based on an actual patient case provided by Peter Ottavio, DO.

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.

Wakix® pitolisant tablets

Please see Important Safety Information continued on following pages and accompanying Full Prescribing Information.

Abby
24-year-old computer programmer

Why WAKIX?

- First and only histaminergic treatment for EDS or cataplexy in narcolepsy
- No clinically important PK interactions with modafinil or sodium oxybate
- Not a controlled substance

Setting Patient Expectations

Abby was advised:

- 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
- WAKIX should be taken once daily in the morning upon wakening
- WAKIX should be individually titrated to the effective dosage
- WAKIX is *not* a stimulant
- WAKIX is *not* a controlled substance

WAKIX Titration and Administration

- WAKIX was initiated at a dosage of 8.9 mg once daily and titrated weekly to the maximum recommended dosage of 35.6 mg once daily by Week 3
  - Administered once daily in the morning upon wakening

Clinical Outcome

- At follow-up via telehealth, Abby reported reductions in EDS and cataplexy at a stable dosage of 35.6 mg once daily
  - ESS score of 13

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

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

Important Safety Information

Warnings and Precautions

- 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).

Adverse Reactions

- In the placebo-controlled clinical trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and 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 infection, musculoskeletal pain, heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash.

Wakix® pitolisant tablets

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Why WAKIX® (pitolisant)?

- First and only **histaminergic** treatment for EDS or cataplexy in narcolepsy
- **Not a controlled substance**
- **Significantly reduced EDS** and **significantly fewer cataplexy attacks** versus placebo in clinical studies
- **Established** safety and tolerability profile in clinical studies
- Convenient **once-daily** morning dosing

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.

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.

Visit **WAKIXhcp.com** to learn more and download the Prescription Referral Form

HARMONY BIOSCIENCES

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Wakix® pitolisant tablets