



## Mary

Age: 60

Occupation:

Office Assistant

Diagnosis:

Narcolepsy with cataplexy (narcolepsy type 1; diagnosed 6 years ago)

Reason for visit:

- Ongoing EDS
- Cataplexy

## Ongoing Symptoms

- Reports ongoing EDS
  - Sometimes dozes off at reception desk at work; ESS score of 16
- Recent increase in cataplexy due to stress at home
  - Reports “clumsiness,” knee buckling; ~8 attacks per week

## Clinical History

- Depression (diagnosed 8 years ago)
- Narcolepsy with cataplexy (narcolepsy type 1; diagnosed 6 years ago after hypersomnia remained following treatment of depression)
  - Mean sleep latency 5 min and 2 SOREMPs on MSLT
  - ESS score of 19
  - History of cataplexy (eg, dropping boxes at work) with multiple emotions
  - No evidence of other primary sleep disorders on PSG or during clinical interview
- GAD
- Panic disorder

## Previous Medications

- Sodium oxybate for EDS and cataplexy in narcolepsy
- Modafinil for EDS in narcolepsy

## Current Medications

- Stimulant for EDS in narcolepsy
- Paroxetine for depression, GAD, and panic disorder

## Treatment Decision

- Initiated WAKIX to treat EDS and cataplexy in narcolepsy

EDS, excessive daytime sleepiness; ESS, Epworth Sleepiness Scale; GAD, generalized anxiety disorder; 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 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:



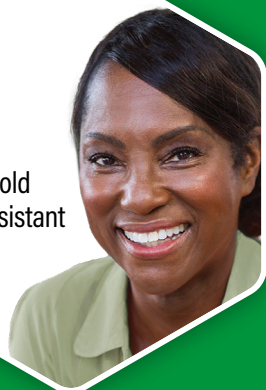
**Debra Stultz, MD**

Psychiatrist & Sleep Specialist  
Stultz Sleep & Behavioral Health  
Barboursville, WV

**Wakix**  
pitolisant tablets

## Mary

60-year-old  
office assistant



## Why WAKIX?

- Different mechanism of action
- Not a stimulant
- Not a controlled substance

## Setting Patient Expectations

Mary was advised:



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



WAKIX is not a stimulant

## WAKIX Titration and Administration

- WAKIX was initiated at a dosage of 8.9 mg once daily and titrated to 17.8 mg once daily after 7 days
  - Maximum recommended dosage with concomitant strong CYP2D6 inhibitors (eg, paroxetine)
  - Administered once daily in the morning upon waking

## Clinical Outcome

- At her 8-week follow-up, Mary reported reductions in EDS and cataplexy at a stable dosage of 17.8 mg once daily
  - ESS score of 11
  - Approximately 4 cataplexy attacks per week

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; ESS, Epworth Sleepiness Scale.

## 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 adult patients with narcolepsy, like Mary:



## Why WAKIX?



Not a controlled substance



Different mechanism of action



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



No clinically important pharmacokinetic (PK) interactions with modafinil or sodium oxybate demonstrated in a clinical PK study in adults<sup>1</sup>



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.
- H<sub>1</sub> receptor antagonists that cross the blood-brain barrier may reduce the effectiveness of WAKIX. Patients should avoid centrally acting H<sub>1</sub> 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<sup>2</sup>.
- 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](http://www.fda.gov/medwatch).

#### Reference

1. Data on file. Harmony Biosciences.

Visit [WAKIXhcp.com](http://WAKIXhcp.com) to view more WAKIX patient case studies



WAKIX is a registered trademark of Bioprojet Europe, Ltd.  
Harmony Biosciences name and logo are registered trademarks.  
© 2024 Harmony Biosciences. All rights reserved.  
US-WAK-2400485/Sep 2024



Please see Important Safety Information throughout and accompanying [Full Prescribing Information](#).