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 (e.g., 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.
Based on an actual patient case provided by Debra Stultz, MD.

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

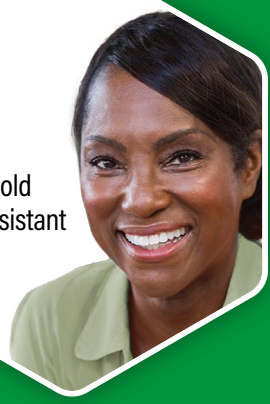
- WAKIX is contraindicated in patients with known hypersensitivity to pitolisant or any component of the formulation. Anaphylaxis has been reported. WAKIX is also contraindicated in patients with severe hepatic impairment.

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.
- 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).

Wakix® pitolisant tablets

Please see Important Safety Information throughout and accompanying Full Prescribing Information.



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 as soon as she wakes up

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 (e.g., paroxetine)
  - Administered once daily in the morning upon wakening

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 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.

Wakix® pitolisant tablets

For adult patients with narcolepsy, like Mary:

Why WAKIX?

Wakix® pitolisant tablets

- Different mechanism of action
- Not a controlled substance
- Evaluated in multiple clinical studies and FDA approved in 2019
- Treats both excessive daytime sleepiness (EDS) and cataplexy in adults with narcolepsy with once-daily morning dosing
- Established safety and tolerability profile in clinical studies

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 view more WAKIX patient case studies

HARMONY BIOSCIENCES

Wakix® pitolisant tablets