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Do your adult patients with narcolepsy feel boxed in?

**Indications and Usage**
- WAKIX is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

**Important Safety Information**

**Contraindications**
- WAKIX is 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).

**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 ≥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.

**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).
WAKIX® (pitolisant) Is a First-in-Class Molecule With a Novel Mechanism of Action

First and only histaminergic treatment for patients with excessive daytime sleepiness (EDS) in narcolepsy

- First and only FDA-approved non-scheduled treatment for patients with narcolepsy
- WAKIX is not a stimulant
- No clinically important pharmacokinetic interactions with modafinil or sodium oxybate
- Convenient once-daily morning dosing

BREAK THROUGH with WAKIX®

- 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. 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, LLC at 1-800-833-7460 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Brief Summary on the following pages and Full Prescribing Information at WAKIXHCP.com.

Learn more at WAKIXHCP.com/today
WAKIX® (pitolisant) tablets, for oral use

BRIEF SUMMARY – See full Prescribing Information available at WAKIXHCP.com.

Initial U.S. Approval: 2019

1 INDICATIONS AND USAGE
WAKIX is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy [see Clinical Studies (14)].

2 CONTRAINDICATIONS
WAKIX is contraindicated in patients with severe hepatic impairment. WAKIX is extensively metabolized by the liver and there is a significant increase in WAKIX exposure in patients with moderate hepatic impairment [see Use in Specific Populations (8.6)].

3 WARNINGS AND PRECAUTIONS

5.1 QT Interval Prolongation
WAKIX prolongs the QT interval. The use of WAKIX should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong the QT interval [see Drug Interactions (7.1)]. WAKIX should also be avoided 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 [see Clinical Pharmacology (12.2)]. The risk of QT prolongation may be greater in patients with hepatic or renal impairment due to higher concentrations of pitolisant. 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 [see Dosage and Administration (2.2, 2.3)]. WAKIX is contraindicated in patients with severe hepatic impairment [see Contraindications (4)]. WAKIX is not recommended in patients with end-stage renal disease (ESRD) [see Dosage and Administration (2.3), Use in Specific Populations (8.7), Clinical Pharmacology (12.3)].

6 ADVERSE REACTIONS
The following adverse reactions are discussed in more detail in other sections of the labeling:

• QT Interval Prolongation [see Warnings and Precautions (5.1)]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In the clinical trials for narcolepsy, 172 patients were treated with WAKIX in placebo-controlled trials for up to 8 weeks and in open-label extension trials for up to 5 years. In trials in which WAKIX was directly compared to placebo, 6 of the 152 patients (3.9%) who received WAKIX and 4 of the 114 patients (3.5%) who received placebo discontinued due to an adverse event.

Most Common Adverse Reactions
In the placebo-controlled clinical trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions (occurring in ≥5% of patients and at twice the rate of placebo) with the use of WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Table 1 presents the adverse reactions that occurred at a rate of ≥2% in patients treated with WAKIX and more frequently than in patients treated with placebo in the placebo-controlled clinical trials in narcolepsy.

Table 1: Adverse Reactions That Occurred in ≥2% of WAKIX-Treated Patients and More Frequently than in Placebo-Treated Patients in Three Placebo-controlled Narcolepsy Studies

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>WAKIX (n=152)</th>
<th>Placebo (n=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache*</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Insomnia*</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Nausea</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Upper respiratory tract infection*</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Musculoskeletal pain*</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Anxiety*</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Heart rate increased*</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Hallucinations*</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Irritability</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Abdominal pain*</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Sleep disturbance*</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Cataplexy</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Rash*</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

* The following terms were combined:

Abdominal pain includes: abdominal discomfort; abdominal pain; abdominal pain upper

Anxiety includes: anxiety; nervousness; stress; stress at work

Hallucinations includes: hallucination; hallucination visual; hypnagogic hallucination

Headache includes: cluster headache; headache; migraine; premenstrual headache; tension headache

Heart rate increased includes: heart rate increased; sinus tachycardia; tachycardia

Insomnia includes: initial insomnia; insomnia; middle insomnia; poor quality sleep

Musculoskeletal pain includes: arthralgia; back pain; carpal tunnel syndrome; limb discomfort; musculoskeletal pain; myalgia; neck pain; osteoarthritis; pain in extremity; sciatica

Rash includes: eczema; erythema migrans; rash; urticaria

Sleep disturbance includes: dysomnia; sleep disorder; sleep paralysis; sleep talking

Upper respiratory infection includes: pharyngitis; rhinitis; sinusitis; upper respiratory tract infection; upper respiratory tract inflammation; viral upper respiratory tract infection

6.2 Postmarketing Experience
The following adverse reactions have been identified during post-approval use of WAKIX outside of the United States. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

General disorders and administration site conditions: fatigue

Investigations: weight increased

Nervous system disorders: epilepsy

Psychiatric disorders: abnormal behavior, abnormal dreams, anhedonia, bipolar disorder, depression, depressed mood, nightmare, sleep disorder, suicide attempt, suicidal ideation

Skin and subcutaneous tissue disorders: pruritus

7 DRUG INTERACTIONS

7.1 Drugs Having Clinically Important Interactions with WAKIX

Table 2: Clinically Significant Drug Interactions with WAKIX

<table>
<thead>
<tr>
<th>Effect of Other Drugs on WAKIX</th>
<th>Clinical Implication</th>
<th>Prevention or Management</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong CYP2D6 Inhibitors</td>
<td>Concomitant administration of WAKIX with strong CYP2D6 inhibitors increases pitolisant exposure by 2.2-fold.</td>
<td>Reduce the dose of WAKIX by half [see Dosage and Administration (2.4), Clinical Pharmacology (12.3)].</td>
<td>paroxetine, fluoxetine, bupropion</td>
</tr>
<tr>
<td>Strong CYP3A4 Inducers</td>
<td>Concomitant use of WAKIX with strong CYP3A4 inducers decreases exposure of pitolisant by 50%.</td>
<td>Assess for loss of efficacy after initiation of a strong CYP3A4 inducer. For patients stable on WAKIX 8.9 mg or 17.8 mg once daily, increase the dose of WAKIX to reach double the original daily dose (i.e., 17.8 mg or 35.6 mg, respectively) over 7 days. If concomitant dosing of a strong CYP3A4 inducer is discontinued, decrease WAKIX dosage by half [see Dosage and Administration (2.4), Clinical Pharmacology (12.3)].</td>
<td>rifampin, carbamazepine, phenytoin</td>
</tr>
</tbody>
</table>

Histamine-1 (H1) Receptor Antagonists

<table>
<thead>
<tr>
<th>Clinical Implication</th>
<th>Prevention or Management</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>WAKIX increases the levels of histamine in the brain; therefore, H1 receptor antagonists that cross the blood-brain barrier may reduce the effectiveness of WAKIX.</td>
<td>Avoid centrally acting H1 receptor antagonists.</td>
<td>pheniramine maleate, diphenhydramine, promethazine (anti-histamines) imipramine, chlorpromazine, mirtazapine (tri or tetracyclic antidepressants)</td>
</tr>
</tbody>
</table>
Clinical Implication: The concomitant use of drugs that prolong the QT interval may add to the QT effects of WAKIX and increase the risk of cardiac arrhythmia.

Prevention or Management: Avoid the use of WAKIX in combination with other drugs known to prolong the QT interval [see Warnings and Precautions (5.1)].

Examples: Class 1A antiarrhythmics: quinidine, procainamide, disopyramide; Class 3 antiarrhythmics: amiodarone, sotalol; Antipsychotics: ziprasidone, chlorpromazine, thioridazine; Antibiotics: moxifloxacin

Effect of WAKIX on Other Drugs

Sensitive CYP3A4 Substrates

Clinical Implication: WAKIX is a borderline/weak inducer of CYP3A4. Therefore, reduced effectiveness of sensitive CYP3A4 substrates may occur when used concomitantly with WAKIX [see Clinical Pharmacology (12.3)].

Prevention or Management: 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 discontinuation of therapy.

Examples: midazolam, hormonal contraceptives, cyclosporine

7.2 Drugs Having No Clinically Important Interactions with WAKIX

A clinical study was conducted to evaluate the concomitant use of WAKIX with modafinil or sodium oxybate. This study demonstrated no clinically relevant effect of modafinil or sodium oxybate on the pharmacokinetics of WAKIX and no effect of WAKIX on the pharmacokinetics of modafinil or sodium oxybate [see Clinical Pharmacology (12.3)].

A clinical study showed that strong CYP3A4 inhibitors (e.g., ketoconazole, grapefruit juice) have no effect on the pharmacokinetics of WAKIX [see Clinical Pharmacology (12.3)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

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.

Risk Summary

Available case reports from clinical trials and postmarketing reports with WAKIX use in pregnant women have not determined a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. In animal reproductive studies, administration of pitolisant during organogenesis caused maternal and embryofetal toxicity in rats and rabbits at doses ≥13 and ≥4 times the maximum recommended human dose (MRHD) of 35.6 mg based on mg/m² body surface area, respectively. Oral administration of pitolisant to female rats during pregnancy and lactation adversely affected maternal and fetal health and produced developmental delay at doses ≥13 times the MRHD, based on mg/m² body surface area and increased the incidence of major malformations at 22 times the MRHD [see Data in full Prescribing Information, available at WAKIXHCP.com].

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

There are no data on the presence of pitolisant in human milk, the effects on the breastfed infant, or the effect of this drug on milk production. Pitolisant is present in the milk of lactating rats [see Data in full Prescribing Information, available at WAKIXHCP.com]. When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for WAKIX and any potential adverse effects on the breastfed child from WAKIX or from the underlying maternal condition.

8.3 Females and Males of Reproductive Potential

Contraception

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 [see Drug Interactions (7.1), Clinical Pharmacology (12.3)].

8.4 Pediatric Use

The safety and effectiveness of WAKIX in pediatric patients have not been established. Limited pharmacokinetic data from 24 pediatric patients with narcolepsy (ages 7 to <18 years) receiving a single dose of WAKIX suggest that pediatric patients have higher exposure to pitolisant than adults. The exposure (Cₘₐₓ and AUC) of pitolisant was 2-fold higher in pediatric patients 12 to <18 years and 3-fold higher in pediatric patients 7 to <12 years compared to adults.

8.5 Geriatric Use

Limited pharmacokinetic data are available in healthy elderly subjects. A pharmacokinetic study that compared 12 elderly subjects (age 68 to 82 years) to 12 healthy adults (age 18 to 45 years) did not reveal any significant differences in drug exposure [see Clinical Pharmacology (12.3)].

Of the total number of patients with narcolepsy in clinical studies of WAKIX, 14 patients (5%) were ≥65 years old. No overall differences in safety or effectiveness were observed between these patients and younger patients in these clinical trials, but greater sensitivity of some older individuals cannot be ruled out. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, and cardiac function, concomitant diseases, and other drug therapy.

8.6 Hepatic Impairment

WAKIX is contraindicated in patients with severe hepatic impairment (Child-Pugh C) as it has not been studied in this population. WAKIX is extensively metabolized by the liver and there is a significant increase in WAKIX exposure in patients with moderate hepatic impairment [see Contraindications (4), Clinical Pharmacology (12.3)].

Monitor patients with moderate hepatic impairment (Child-Pugh B) and adjust the dosage of WAKIX [see Dosage and Administration (2.2)].

Monitor patients with mild hepatic impairment (Child-Pugh A). No dosage adjustment of WAKIX is recommended in patients with mild hepatic impairment.

8.7 Renal Impairment

The pharmacokinetics of WAKIX in patients with end-stage renal disease (ESRD) (eGFR of <15 mL/minute/1.73 m²) is unknown [see Clinical Pharmacology (12.3)]. Therefore, WAKIX is not recommended in patients with ESRD [see Dosage and Administration (2.3), Warnings and Precautions (5.1)].

Dosage adjustment of WAKIX is recommended in patients with moderate (eGFR 30 to 59 mL/minute/1.73 m²) and severe (eGFR 15 to 29 mL/minute/1.73 m²) renal impairment [see Dosage and Administration (2.3)].

8.8 CYP2D6 Poor Metabolizers

Dosage reduction is recommended in patients known to be poor CYP2D6 metabolizers because these patients have higher pitolisant concentrations than normal CYP2D6 metabolizers [see Dosage and Administration (2.2), Clinical Pharmacology (12.3, 12.5)].

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of pitolisant in excessive daytime sleepiness (EDS) in adult patients with narcolepsy is unclear. However, its efficacy could be mediated through its activity as an antagonist/inverse agonist at histamine-3 (H₃) receptors.

12.2 Pharmacodynamics

Pitolisant binds to H₃ receptors with a high affinity (Kᵢ = 1 nM) and has no appreciable binding to other histamine receptors (H₁, H₂, or H₄ receptors; Kᵢ >10 μM).

Cardiac Electrophysiology

WAKIX at the highest recommended dosage (i.e., 35.6 mg daily) led to a QTc increase of 4.2 msec. Exposures 3.8-fold higher than achieved at the highest recommended dose increase QTc 16 msec (mean) [see Warnings and Precautions (5.1)].
Sleep in health care workers

Nurses’ sleep, work hours, and patient care quality, and safety

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Sleep hygiene in paramedics: What do they know and what do they do?

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Sleep in the military

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Toby D. Elliman, PhD, Molly E. Schwalb, MPH, and Amy B. Adler, PhD

Driving safety, work, and sleep

Fighting fatigue: A conceptual model of driver sleep in the gig economy

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Sleep misalignment and circadian rhythm impairment in long-haul bus drivers under a two-up operations system

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Evaluating the quality and duration of sleep using actigraphy in petroleum industry shift workers

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NSF covid statement
Sleep in a time of pandemic - a position statement from the national sleep foundation
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The Sleep Health Times
The Sleep Health Times