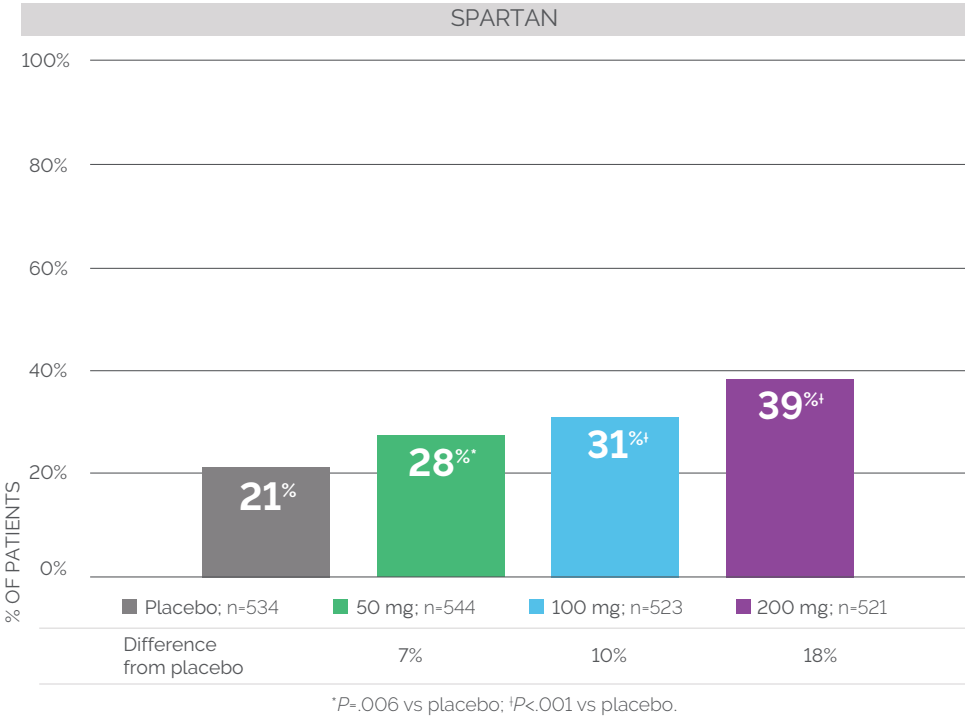
OPEN YOUR PATIENTS' WORLD TO THE POSSIBILITY OF **PAIN FREEDOM**[1]

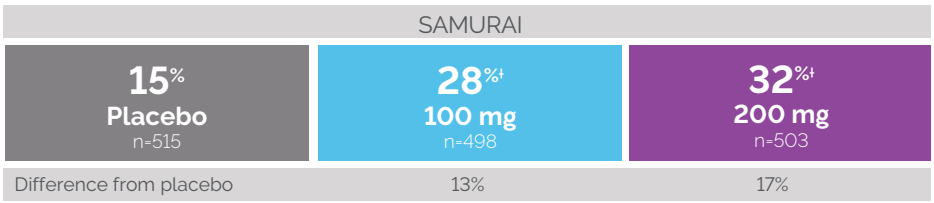
REYVOW™
(lasmiditan) Ⓥ
tablets 50mg, 100mg

REYVOW CAN DELIVER FAST AND COMPLETE ELIMINATION OF MIGRAINE PAIN[1]

RESULTS FROM 2 STUDIES, % OF PATIENTS WHO ACHIEVED PAIN FREEDOM AT 2 HOURS WITH REYVOW VS PLACEBO[1]



*P=.006 vs placebo; †P<.001 vs placebo.



†P<.001 vs placebo.

Study Design[1-7]

REYVOW, a ditan, is a high-affinity 5-HT_{1F} receptor agonist and a tablet that was evaluated in 2 randomized, double-blind, placebo-controlled, single-attack trials.

- 4439 patients age 18 and older were dosed (REYVOW=3177; placebo=1262), including those with:
  - ≥2 cardiovascular risk factors (41%)
  - Concomitant use of migraine preventive drugs (22%)
  - Concomitant use of serotonergic medication (22%)
  - Prior triptan exposure within the past 3 months (37%)
- All patients had:
  - History of migraine for at least 1 year
  - 3-8 migraine attacks/month
  - MIDAS‡ score ≥11 (pooled median was 25)

Patients were instructed to take the study drug within 4 hours of headache onset when the pain was moderate to severe.

Patients were allowed to take a rescue medication 2 hours after taking study drug; however, opioids, barbiturates, triptans, and ergots were not allowed within 24 hours of study drug administration.

The primary endpoint in both studies was pain freedom, defined as a reduction of moderate or severe migraine pain to no pain at 2 hours.

Doses evaluated:
100 mg, 200 mg (SAMURAI)
50 mg, 100 mg, 200 mg (SPARTAN)

‡Migraine Disability Assessment.

INDICATION AND USAGE
REYVOW is indicated for the acute treatment of migraine with or without aura in adults.

LIMITATIONS OF USE
REYVOW is not indicated for the preventive treatment of migraine.

SELECT IMPORTANT SAFETY INFORMATION

Driving Impairment
REYVOW may cause significant driving impairment. More sleepiness was reported at 8 hours following a single dose of REYVOW compared to placebo. Advise patients not to engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery, for at least 8 hours after each dose of REYVOW. Patients who cannot follow this advice should not take REYVOW. Prescribers and patients should be aware that patients may not be able to assess their own driving competence and the degree of impairment caused by REYVOW.

Please see Important Safety Information on the next page and see Full Prescribing Information and Medication Guide.

Explore more at **REYVOW.COM/HCP**

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Driving Impairment
REYVOW may cause significant driving impairment. In a driving study, administration of single 50 mg, 100 mg, or 200 mg doses of REYVOW significantly impaired subjects' ability to drive. Additionally, more sleepiness was reported at 8 hours following a single dose of REYVOW compared to placebo. Advise patients not to engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery, for at least 8 hours after each dose of REYVOW. Patients who cannot follow this advice should not take REYVOW. Prescribers and patients should be aware that patients may not be able to assess their own driving competence and the degree of impairment caused by REYVOW.

Central Nervous System Depression
REYVOW may cause central nervous system (CNS) depression, including dizziness and sedation. Because of the potential for REYVOW to cause sedation, other cognitive and/or neuropsychiatric adverse reactions, and driving impairment, REYVOW should be used with caution if used in combination with alcohol or other CNS depressants. Patients should be warned against driving and other activities requiring complete mental alertness for at least 8 hours after REYVOW is taken.

Serotonin Syndrome
In clinical trials, reactions consistent with serotonin syndrome were reported in patients treated with REYVOW who were not taking any other drugs associated with serotonin syndrome. Serotonin syndrome may also occur with REYVOW during coadministration with serotonergic drugs [e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and monoamine oxidase (MAO) inhibitors]. Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular signs (e.g., hyperreflexia, incoordination), and/or gastrointestinal signs and symptoms (e.g., nausea, vomiting, diarrhea). The onset of symptoms usually occurs within minutes to hours of receiving a new or a greater dose of a serotonergic medication. Discontinue REYVOW if serotonin syndrome is suspected.

Medication Overuse Headache
Overuse of acute migraine drugs (e.g., ergotamines, triptans, opioids, or a combination of drugs for 10 or more days per month) may lead to exacerbation of headache (i.e., medication overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in frequency of migraine attacks. Detoxification of patients including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

ADVERSE REACTIONS

The most common adverse reactions associated with REYVOW (≥2% and greater than placebo in clinical studies) were dizziness, fatigue, paresthesia, sedation, nausea and/or vomiting, and muscle weakness.

DRUG ABUSE AND DEPENDENCE

REYVOW contains lasmiditan, a Schedule V controlled substance.

Abuse
In a human abuse potential study in recreational poly-drug users (n=58), single oral therapeutic doses (100 mg and 200 mg) and a supratherapeutic dose (400 mg) of REYVOW were compared to alprazolam (2 mg) (C-IV) and placebo. With all doses of REYVOW, subjects reported statistically significantly higher "drug liking" scores than placebo, indicating that REYVOW has abuse potential. Subjects who received REYVOW reported statistically significantly lower "drug liking" scores than alprazolam. Euphoric mood occurred to a similar extent with REYVOW 200 mg, REYVOW 400 mg, and alprazolam 2 mg (43-49%). A feeling of relaxation was noted in more subjects on alprazolam (22.6%) than with any dose of REYVOW (7-11%). Phase 2 and 3 studies indicate that, at therapeutic doses, REYVOW produced adverse events of euphoria and hallucinations to a greater extent than placebo. However, these events occur at a low frequency (about 1% of patients). Evaluate patients for risk of drug abuse and observe them for signs of lasmiditan misuse or abuse.

Dependence
Physical withdrawal was not observed in healthy subjects following abrupt cessation after 7 daily doses of lasmiditan 200 mg or 400 mg.

Please see Full Prescribing Information and Medication Guide.

LM HCP ISI 11JAN2020

References: 1. REYVOW [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC. **2.** Kuca B, Silberstein SB, Wietecha L, et al. Lasmiditan is an effective acute treatment for migraine A phase 3 randomized study. *Neurology*. 2018;91:e2222-e2232. **3.** Goadsby PJ, Wietecha LA, Dennehy EB, et al. Phase 3 randomized, placebo-controlled, double-blind study of lasmiditan for acute treatment of migraine. *Brain*. 2019;142:1894-1904. **4.** Shapiro RE, Hochstetler HM, Dennehy EB, et al. Lasmiditan for acute treatment of migraine in patients with cardiovascular risk factors: post-hoc analysis of pooled results from 2 randomized, double-blind, placebo-controlled, phase 3 trials. *J Headache Pain*. 2019;20:90. **5.** Data on File. Indianapolis, IN: Lilly USA, LLC. DOF-LM-US-0018. **6.** Data on File. Indianapolis, IN: Lilly USA, LLC. DOF-LM-US-0005. **7.** Data on File. Indianapolis, IN: Lilly USA, LLC. DOF-LM-US-0012.

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Lilly