La Renon

SILENCING THE STORM

LASMIDIREN

50 100

Lasmiditan 50 mg and 100 mg Tablets

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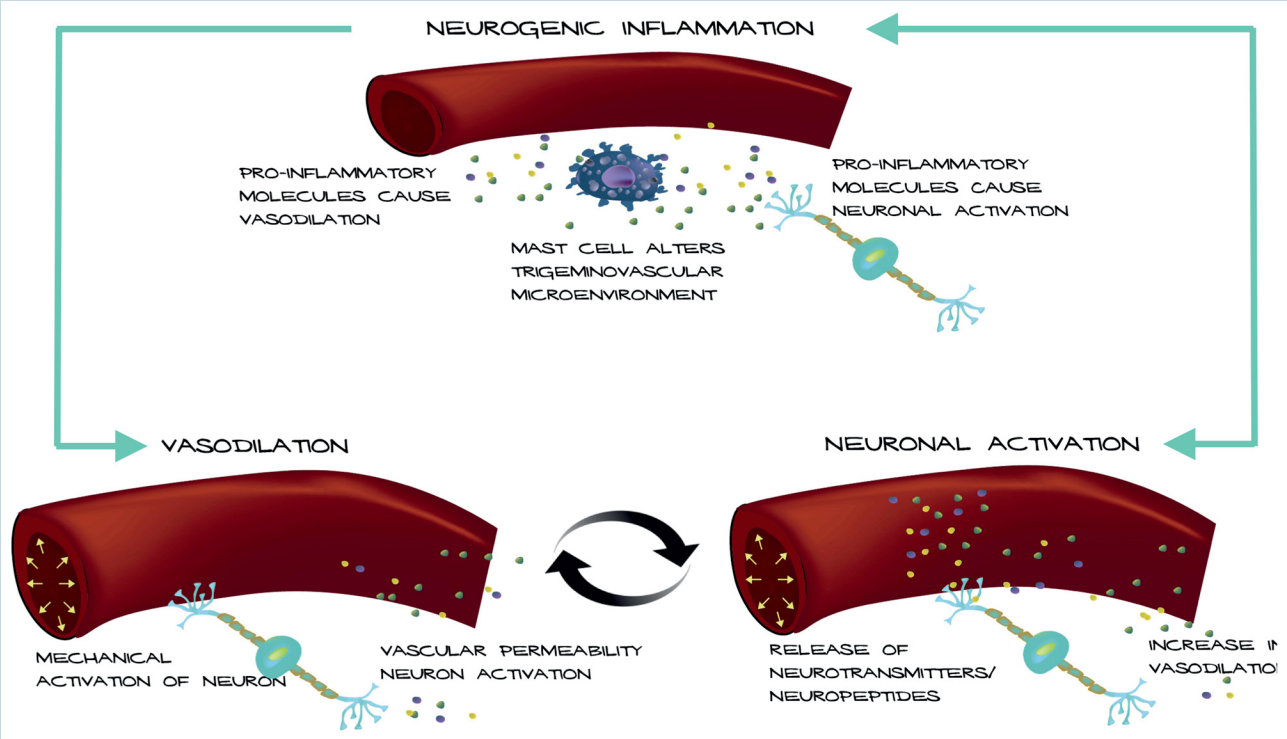
BACKGROUND :

- As per WHO, Migraine is a common neurological disease, ranked as the second highest cause of disability worldwide.[1]
- Triptans target on 5HT 1B/1D receptors, that are also present in coronary arteries which leads to cardiac vasoconstriction, makes this class of drugs contraindicated in patients with cardiovascular risk factors.[2]
- To overcome this gap, a new class of drugs called “neurally acting anti-migraine agents or Ditans” have been developed to act without vasoconstriction.[2]
- Lasmiditan, a highly selective agonist for 5HT1F receptors, is the first and only drug in the class of ditans to finish 2 phase III trials. Due to low cardiovascular adverse effects, it can be used in patients having cardiovascular risk factors.[2]

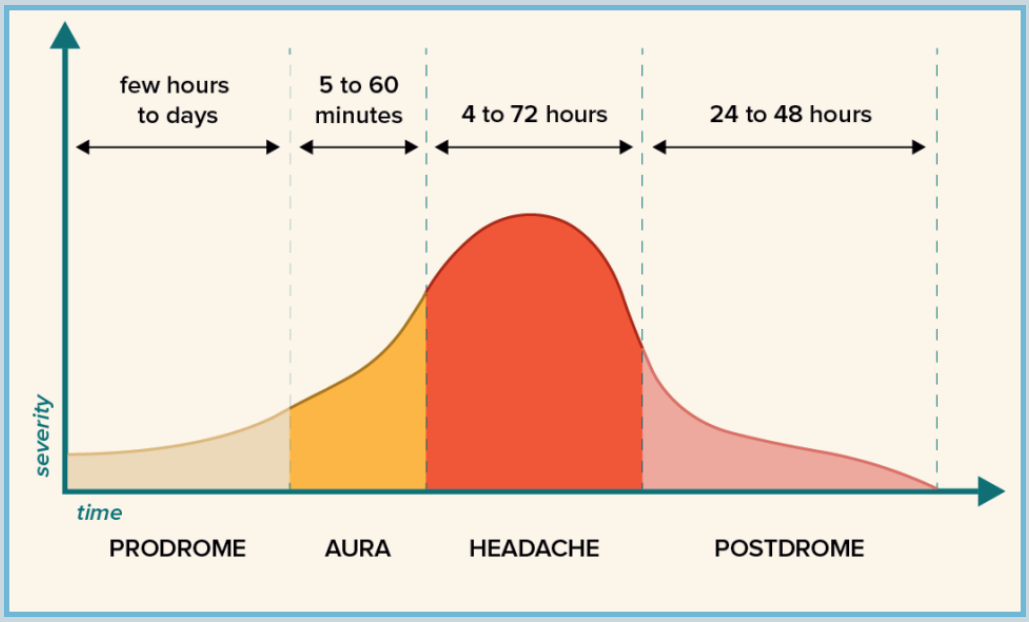
References :
1. Brain. 2019 Jul 1;142(7):1894-1904. I 2. Annals of Indian Academy of Neurology 24(2):p 155-163, Mar–Apr 2021.

PATHOPHYSIOLOGY OF MIGRAINE :



Reference :
Front Cell Neurosci. 2018 Aug 3:12:233.

PHASES OF MIGRAINE :



KEY FEATURES:

LASMIDITAN

It is a novel **selective serotonin 5-HT1F receptor agonist without the vasoconstrictor activity.**

It is the **first neurally acting** drug for the treatment of acute migraine.

It attains **headache pain freedom and most bothersome symptom (MBS) freedom at 2 hours.**

Its **efficacy is not affected by cardio vascular risk factors.**

HUMAN TRIAL / STUDY OF LASMIDITAN ON MIGRAINE PATIENTS

SR. NO.	TITLE	NO. OF PATIENTS	DOSE	CONCLUSION	TYPE OF TRIAL	REFERENCE
01	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	4,439 patients	Lasmiditan 200 mg, 100 mg, or 50 mg (SPARTAN only) or placebo	Lasmiditan is considered to be safe and efficacious in the treatment of patients with CVRFs.	Phase 3, randomized, double-blind, placebo-controlled trials	*J Headache Pain . 2019 Aug 29;20(1):90.*
02	Sustained responses to lasmiditan: Results from post-hoc analyses of two Phase 3 randomized clinical trials for acute treatment of migraine	4,439 patients	Lasmiditan 200 mg, 100 mg or 50 mg versus placebo	Lasmiditan is effective for the acute treatment of migraine attacks with sustained efficacy on all aspects of acute migraine attacks at 24 and 48 hours.	Phase 3, randomized, double-blind, placebo-controlled studies	*Cephalalgia. 2019 ;39(12):1569-1576.*
03	Phase 3 randomized, placebo-controlled, double-blind study of lasmiditan for acute treatment of migraine	2,869 patients	Lasmiditan (200 mg, 100 mg, 50 mg) or placebo for the first dose (in a 1:1:1:1 ratio) and the second dose of lasmiditan or placebo (in a 2:1 ratio)	Lasmiditan is effective at 2 h post-dose for acute treatment of migraine at all oral doses tested.	Phase 3 randomized, double-blind, placebo-controlled study	*BRAIN 2019: 142; 1894–1904*
04	Lasmiditan for the acute treatment of migraine: Subgroup analyses by prior response to triptans	3,981 patients	Lasmiditan 50 mg (SPARTAN only), 100 mg, 200 mg, or placebo.	Lasmiditan demonstrated efficacy in both patients with a good response and those with an insufficient response to prior triptan therapy, as well as in those who were triptan naive.	Two similarly designed Phase 3, prospective, randomized, double-blind, placebo-controlled trials	*Cephalalgia . 2020 Jan;40(1):19-27.*
05	Lasmiditan is an effective acute treatment for migraine	1,856 patients	Lasmiditan 200 mg, lasmiditan 100 mg, or placebo.	Lasmiditan dosed at 200 and 100 mg is efficacious and well tolerated in the treatment of acute migraine among patients with a high level of cardiovascular risk factors.	Randomized, double-blind, placebo-controlled study	*Neurology® 2018;91:e1-e11.*
06	Randomized, controlled trial of lasmiditan over four migraine attacks: Findings from the CENTURION study	1,471 patients	a) lasmiditan 100 mg; b) lasmiditan 200 mg; or c) a control group, which received placebo for three attacks and lasmiditan 50 mg for either attack 3 or attack 4	Lasmiditan 100 mg and 200 mg shows early, sustained efficacy and consistency of response across multiple attacks.	Multicenter, randomized, placebo controlled, double-blind modified parallel Phase 3 study	*Cephalalgia 2021, Vol. 41(3) 294–304*
07	Safety profile of lasmiditan in patients with migraine in an Asian population	846 Participants	7:3:7:6 ratio to placebo or lasmiditan 50 mg, 1 00 mg, or 200 mg	Lasmiditan represent a useful and well-tolerated acute treatment option for smaller (body mass index <30 kg/m2) patients and Asian patients with migraine.	Prospective, multicenter, randomized, double-blind, placebo-controlled phase 2 study	*Expert Opin Drug Saf . 2022 Jul 12;1-11.*
08	Phase 2 randomized placebo-controlled study of lasmiditan for the acute treatment of migraine in Japanese patients	863 patients	7:3:7:6 to receive oral placebo or lasmiditan 50 mg, 100 mg, or 200 mg	A single dose of lasmiditan is effective in improving or eliminating moderate-to-severe migraine pain and migraine-associated symptoms in Japanese patients experiencing migraine with or without aura.	Multicenter, randomized, double-blind, placebo-controlled, phase 2 study	*Headache . 2021 May;61(5):755-765.*
09	Efficacy and tolerability of lasmiditan, an oral 5-HT1F receptor agonist, for the acute treatment of migraine: a phase 2 randomised, placebo-controlled, parallel-group, dose-ranging study	512 patients	50 mg, 100 mg, 200 mg, or 400 mg lasmiditan, or placebo	Oral lasmiditan seems to be safe and effective in the acute treatment of migraine.	Multicentre, double-blind, parallel-group, dose-ranging study	*Lancet Neurol . 2012 May;11(5):405-13.*
10	Lasmiditan efficacy in migraine attacks with mild vs. moderate or severe pain	-	In SAMURAI, participants were randomized (1:1:1) to a single dose of LTN 200 mg, LTN 100mg or placebo. In SPARTAN, participants were randomized (1:1:1:1) to receive a singledose of LTN 200 mg, LTN 100 mg, LTN 50mg or placebo.	The result suggested better efficacy outcomes when LTN treatment was initiated at mild vs. moderate to severe pain.	(SAMURAI and SPARTAN) prospective, randomized, double-blind, multicenter, single-attack, phase 3 studies	*Curr Med Res Opin . 2021 Jun;37(6):1031-1038.*

CLINICAL DATA OBSERVATIONS

01 Lasmiditan 200 & 100 mg is efficacious and well tolerated in the treatment of acute migraine among patients with a high level of cardiovascular risk factors.[1]

02 Lasmiditan 100 mg and 200 mg shows early, sustained efficacy and consistency of response across multiple attacks.[2]

03 It shows efficacy not only in patients who reported a good or insufficient response to triptan therapy, but also in patients who were triptan naive.[3]

04 It is effective for the acute treatment of migraine attacks, with sustained efficacy on all aspects at 24 and 48 hours.[4]

05 All doses of lasmiditan resulted in a significant improvement in migraine-related functional disability, which commenced as early as 1 h post dose and persisted upto 48 h.[5]

06 A single dose of lasmiditan is effective in improving or eliminating moderate-to-severe migraine pain and migraine-associated symptoms in Japanese patients experiencing migraine with or without aura.[6]

07 Lasmiditan is effective at 2 h post-dose for acute treatment of migraine at all oral doses tested.[7]

References :
1. Neurology® 2018;91:e1-e11. I 2. Cephalalgia 2021, Vol. 41(3) 294–304 I 3. Cephalalgia. 2020 Jan;40(1):19-27.
4. Cephalalgia. 2019 ;39(12):1569-1576. I 5. Neurol Ther (2020) 9:459–471 I 6. Headache. 2021 May;61(5):755-765. I 7. BRAIN 2019: 142; 1894–1904

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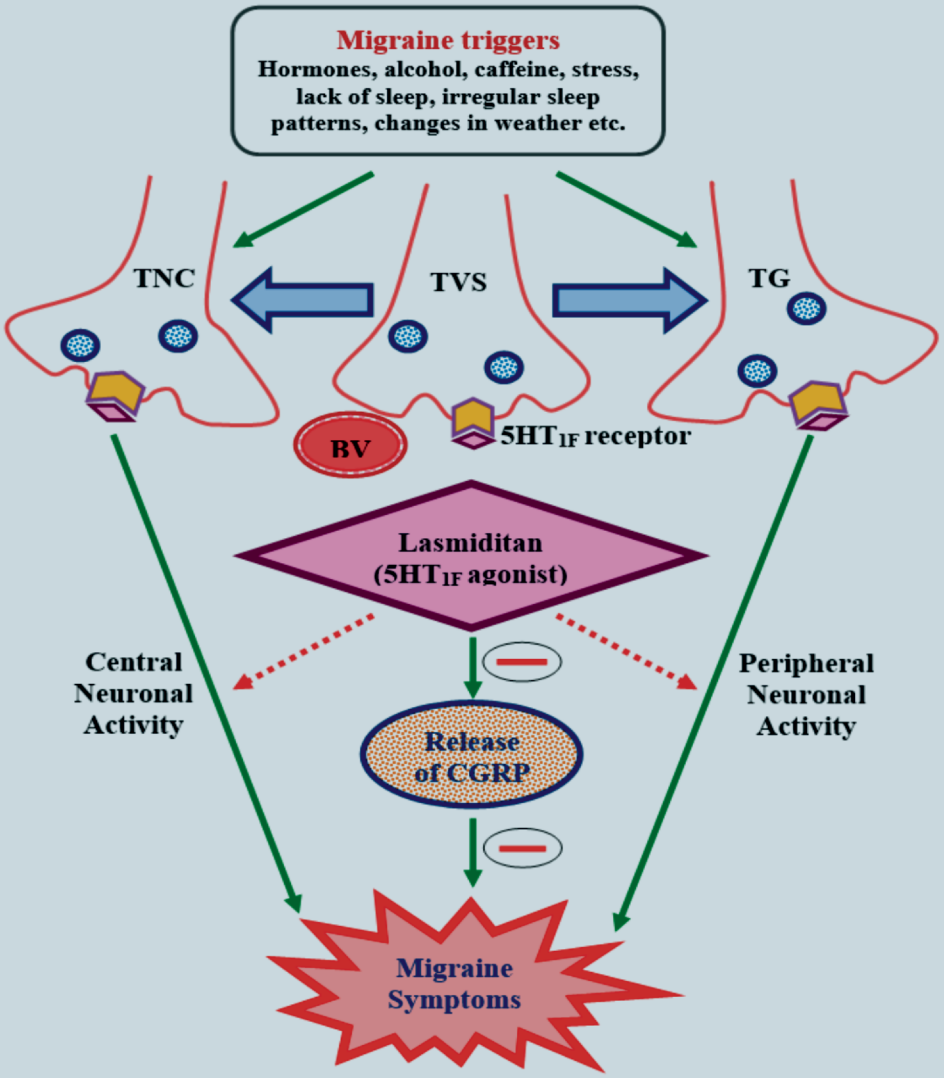
MECHANISM OF ACTION



Solid line arrow indicates activation.
Dotted line arrow or dash symbol in an oval indicate inhibition.
TNC: Trigeminal nucleus caudalis;
TVS: Trigeminal vascular system;
TG: Trigeminal ganglion;
5HT: Serotonin;
BV: Blood vessel;
CGRP: Calcitonin gene related peptide

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DESCRIPTION:

Lasmidiren contain Lasmiditan available in the strength of 50 mg and 100 mg Tablets. Lasmiditan, a centrally-penetrant, highly selective and potent 5-HT1F receptor agonist without vasoconstrictive activity, is a novel acute therapy for migraine.[1]

MECHANISM OF ACTION:

Lasmiditan selectively targets 5-HT1F receptors on neurons in the central and peripheral trigeminal system, decreasing neuropeptide release and inhibiting pain pathways, including the trigeminal nerve.[2]

INDICATION:

Lasmiditan is indicated for the acute treatment of migraine with or without aura in adults.

DOSAGE:

The recommended dose is 50 mg or 100 mg taken orally, as needed. No more than one dose should be taken in 24 hours or as directed by Physician.

PRESENTATION:

Available as a strip of 4 Tablets.

STORAGE:

Store protected from light and moisture **at a temperature not exceeding 25°C.**

References:
1. Brain. 2019 Jul 1;142(7):1894-1904.
2. J Headache Pain. 2019 Aug 29;20(1):90.

La Renon Healthcare Private Limited
207-208 Iscon Elegance, Circle P, Prahlad Nagar Cross Roads,
S.G. Highway, Ahmedabad-380015, Gujarat, India.
Phone : 91-79-66168998 / 26936656 | Fax: +91-66168998
E-mail :info@larenon.com | Web : www.larenon.com

I am: _____
Call me on: _____
Mail me at: _____