

La Renon®



TAME
THE
PAIN



PBREN®

Pregabalin Capsules 50 mg / 75 mg / 150 mg

PBREN®-M

Pregabalin Capsules with Mecobalamin 75 mg & 750 mcg

Background:

Neuropathic Pain is a complex, chronic pain state that usually is accompanied by tissue injury. With neuropathic pain, the nerve fibers themselves might be damaged, dysfunctional, or injured. These damaged nerve fibers send incorrect signals to other pain centers. The impact of a nerve fiber injury includes a change in nerve function both at the site of injury and areas around the injury.

How common is Neuropathic Pain ??

- General population studies, around 7–8% of adults currently have chronic pain with neuropathic characteristics.¹
- 371 million people diagnosed with diabetes mellitus worldwide and a prevalence of 8.3% as per the Diabetes Atlas 2012, diabetes mellitus and approximately 40–50% of the patients developing DPN further develop painful DPN.²
- Approximately 20% (18.7 – 21.4%) of people with cancer have cancer-related neuropathic pain, as a result of either the disease or its treatment.¹
- 33 million people infected with HIV across the world, around 35% have neuropathic pain, which does not respond well to standard treatments.¹
- In the India, studies in 2006, patients with diabetes, 29.2% (586 / 2006) of people with diabetes were found to have DPN.²

Reference:

1. International Association for the Study of Pain; 2014-2015

2. Diabetes Invest; 5: 714–721: 2014

Clinical Effectiveness Of Pbren:

As per Diabet Med.; 2011

A randomized, double-blind, placebo-controlled, multicentre 14 week clinical trial in 317 Japanese patients with diabetic peripheral neuropathy and efficacy was measured by a change of mean pain score from baseline to end-point from patients' daily pain diaries.

Results:

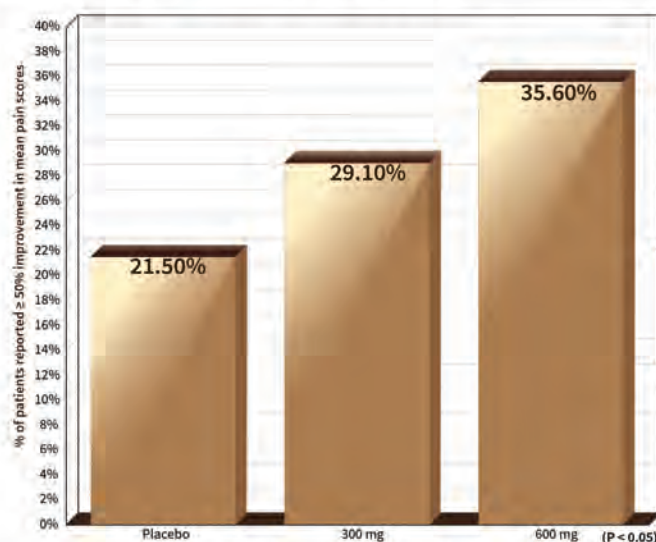
- 29.1 and 35.6% of patients treated with 300 and 600 mg pregabalin/day, respectively, reported $\geq 50\%$ improvement in mean pain scores (vs. 21.5% for placebo).
- Pregabalin produced significant improvements in weekly sleep interference scores, the short-form McGill Pain Questionnaire, the Medical Outcomes Study-Sleep Scale, the 36-item Short-Form Health Survey scale, and the Patient and Clinical Global Impression of Change.
- Patient impressions of numbness, pain and paraesthesia were also significantly improved

Conclusion:

Pregabalin was effective in reducing pain and improving sleep disturbances due to pain, and was well tolerated in Japanese patients with painful DPN.

Reference:

1. Diabet Med. 2011 Jan;28(1):109-16.



Clinical Effectiveness Of Pbren-M:

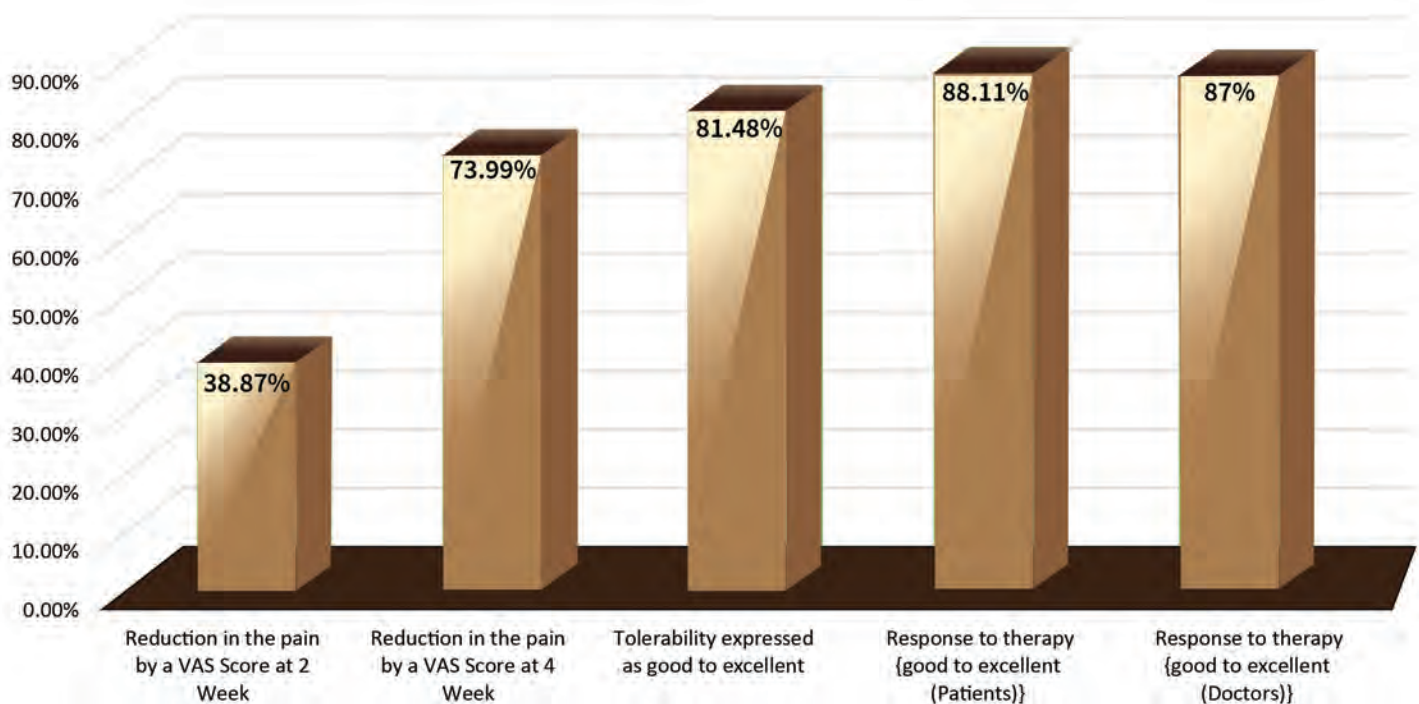
As per *North American Journal of Medical Sciences*; 2012:

Efficacy and Tolerability of a Fixed Dose Combination of Methylcobalamin and Pregabalin in the Management of Painful Neuropathy

- The multi-center open label, non-interventional observational, Phase IV (Post marketing surveillance) trial, in 1525 patients.
- Results assessed by a reduction in the pain by a visual analogue score, tolerability is expressed as good to excellent and response to therapy is expressed as good to excellent.

Results:

- Reduction in the pain from base line (by a visual analogue score): 38.87 and 73.99% at second and fourth week respectively.
- Response to therapy (as good to excellent): 87% doctors and 88.11% patients
- Tolerability (as good to excellent): 81.48% patients



Conclusion:

The finding of the study concludes that a FDC of Methylcobalamin 750 mcg and Pregabalin 75 mg is well tolerated and efficacious in treating the pain of neuropathic origin.

TAME THE PAIN



In Neuropathic Pain,

PBREN®

Pregabalin Capsules 50 mg / 75 mg / 150 mg

PBREN-M®

Pregabalin Capsules with Methylcobalamin 75 mg & 750 mcg

Indication:

PBREN is indicated for –

- A. *Neuropathic pain associated with diabetic peripheral neuropathy (DPN)*
- B. *Postherpetic neuralgia (PHN)*
- C. *Adjunctive therapy for adult patients with partial onset seizures*
- D. *Fibromyalgia*
- E. *Neuropathic pain associated with spinal cord injury*

Mechanism of Action:

Pregabalin: Chemically Pregabalin is described (S)-3-(aminomethyl)-5-methylhexanoic acid. The exact mechanism of action of pregabalin has not been fully understood, it binds to the alpha2-delta (A2D) receptors of an auxiliary subunit associated with voltage-gated calcium channels in central nervous system tissues and thereby inhibits influx of calcium and release of glutamate, norepinephrine substance P, and other neurotransmitters.

Methylcobalamin: Methylcobalamin is active form of vitamin B12 which played a key role in the normal functioning of the brain and nervous system. It can directly participate in homocysteine metabolism. Methylcobalamin exerts its therapeutic effects on neuropathic pain through its neuro-synthesis and neuro-protective actions.

The fixed dose combination of Pregabalin 75 mg/150 mg + Methylcobalamin 750 mcg capsules is approved by DCGI for the treatment of adult patients with peripheral neuropathy.

Dosage:

For all indications, the beginning dose of Pregabalin is 150 mg/day and the Dosing recommendations are:

Indication	Dosing Regimen	Maximum Dose
DPN Pain	3 divided doses per day	300 mg/day within 1 week
PHN	2 or 3 divided doses per day	300 mg/day within 1 week. Maximum dose of 600 mg/day.
Adjunctive Therapy for Adult Patients with Partial Onset Seizures	2 or 3 divided doses per day	Maximum dose of 600 mg/day.
Fibromyalgia	2 divided doses per day	300 mg/day within 1 week. Maximum dose of 450 mg/day.
Neuropathic Pain Associated with Spinal Cord Injury	2 divided doses per day	300 mg/day within 1 week. Maximum dose of 600 mg/day.

Dose should be adjusted in patients with reduced renal function.

Available as – PBREN is available as 50 mg, 75 mg & 150 mg Capsule, PBREN-M is available as Pregabalin 75 mg + Methylcobalamin 750 mcg capsule.

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