

The unhighlighted PAIN BURDEN

Chronic pain, usually defined as pain lasting for 3 months or more, is the leading cause of disability worldwide1.

Up to 1 in 10 suffer from chronic neuropathic pain globally (2,3)



What is **Neuropathic Pain?**

Neuropathic pain:

complex, chronic, severe challenging to treat and manage can impact quality of life limit mobility contribute to depression and social dysfunction.



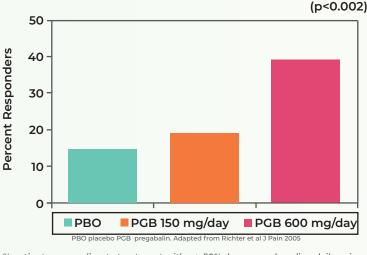
Management of neuropathic pain^{8,9}

- Medical assessment of causes of pain.
- Optimizing Tx of underlying cause for eg improving glycemic control and lifestyle interventions in diabetes.
- Assessment of baseline severity and optimizing pain reduction.
- Improvement of quality of life (eg sleep and mood disorders).
- Pharmacotherapy-Gabapentins including pregabalin as first line therapy.

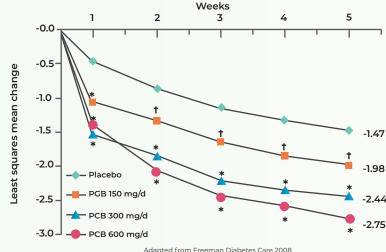
Pregabalin in pDN (peripheral diabetic neuropathy)

Pregabalin significantly provides rapid, sustained decrease in pain scores in pDN 10

In 7 pooled RCTs in pDN, pregabalin was effective as early as Week 1 to significantly decrease pain scores11



% patients responding to treatment with a ≥ 50% decrease n baseline daily pain



Adapted from Freeman Diabetes Care 2008

Change from baseline to week 5 in least-squares mean pain score

Pregabalin improves quality of life in pDN

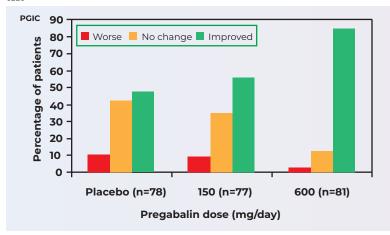
Pregabalin significantly improves sleep and quality of life in terms of reduction of pain in pDN 10,11,12

Patients receiving 600 mg/day pregabalin had significantly lower sleep interference scores starting at week 1 and at end point

-PBO --- PGB 150 mg/d --- PGB 600 mg/d Least-Squares Mean Sleep-Interference Score 2 *P<0.05 **P<0.01 3

Pregabalin 300 mg/day and 600 mg/day significantly improved patients' impression of pain¹⁰

Pregabalin 600 mg/day vs placebo comparison significant, P=0.002, using the CMH

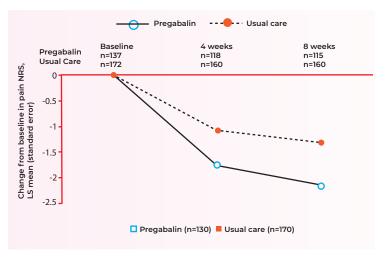


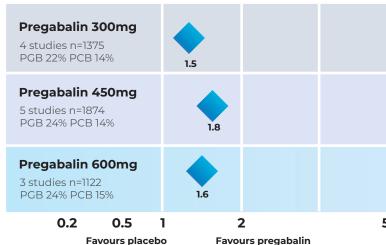
Pregabalin in low back pain with neuropathy

Efficacy of Pregabalin in Fibromyalgia

Pregabalin significantly reduces pain in patients with Low Back Pain with a neuropathic component $^{\rm 13}$

Pregabalin 300 to 600 mg daily significantly reduces pain in about 1 in 10 people with moderate or severe pain from fibromyalgia .





Pregabalin(PGB) vs Placebo(PCB)

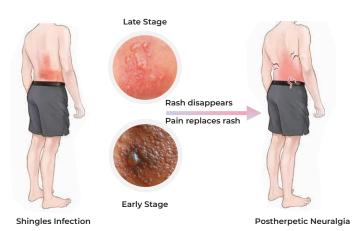
Outcome: At least 50% pain relief -substantial pain relief (% Percentage patients with Outcome)

Efficacy for treatment of pain assessed using pain numerical rating scale (NRS) Adapted from Derry S, et al Cochrane Database Syst Rev. 2016

Pregabalin in Post herpetic neuralgia (PHN)

Persistent Pain in Over **Half of Shingles**Patients

PHN occurs in more than 50% of patients with herpes zoster characterized by persistent (≥ 3 months) lancinating/burning pain, & paraesthesia or near the area of rash.¹⁶



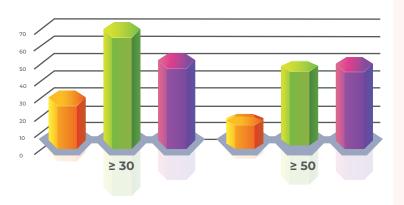
Age-Related Increase in **Postherpetic Neuralgia (PHN)**

58 years old lady with diabetes and normal kidney function. She had chicken pox as a child.



Pregabalin Effective for **Neuropathic Pain in PHN18**

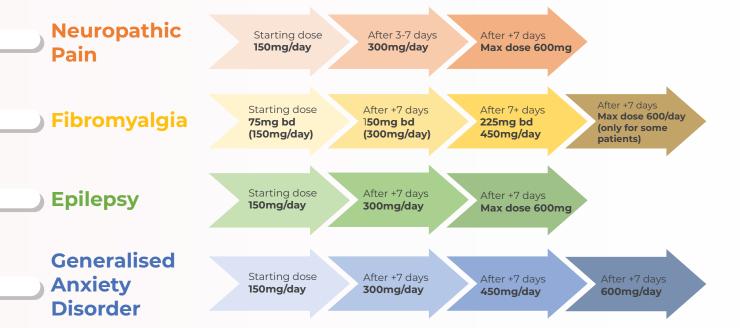
Pregabalin is highly effective and well-tolerated for the treatment of neuropathic pain in PHN18 $\,$



After 1 month.....



Pregabalin in Post herpetic neuralgia (PHN)



Pregabalin is proven bioequivalent to innovator¹⁹

PK Parameters (units)	Acceptance BE Range	90% confidence interval	Result
C _{max} (ng/ml)	80.00%-125.00%	92.25 - 101.87	Bioequivalent
AUC ₀₋₁ (ng.h/ml)	80.00%-125.00%	96.77 - 104.52	Bioequivalent

