



7-10% of the population is affected by Neuropathic Pain¹

1-in-3 diabetic patients are affected by painful Diabetic Peripheral Neuropathy²

1. Posso IdP et al. Epidemiology of neuropathic pain. Rev Dor. São Paulo. 2014;17(Suppl 1):S11-4.

2. Ponirakis G, et al. Prevalence and risk factors for painful diabetic neuropathy in secondary healthcare in Qatar. J Diabetes Investig. 2019;10(6):1558-1564.



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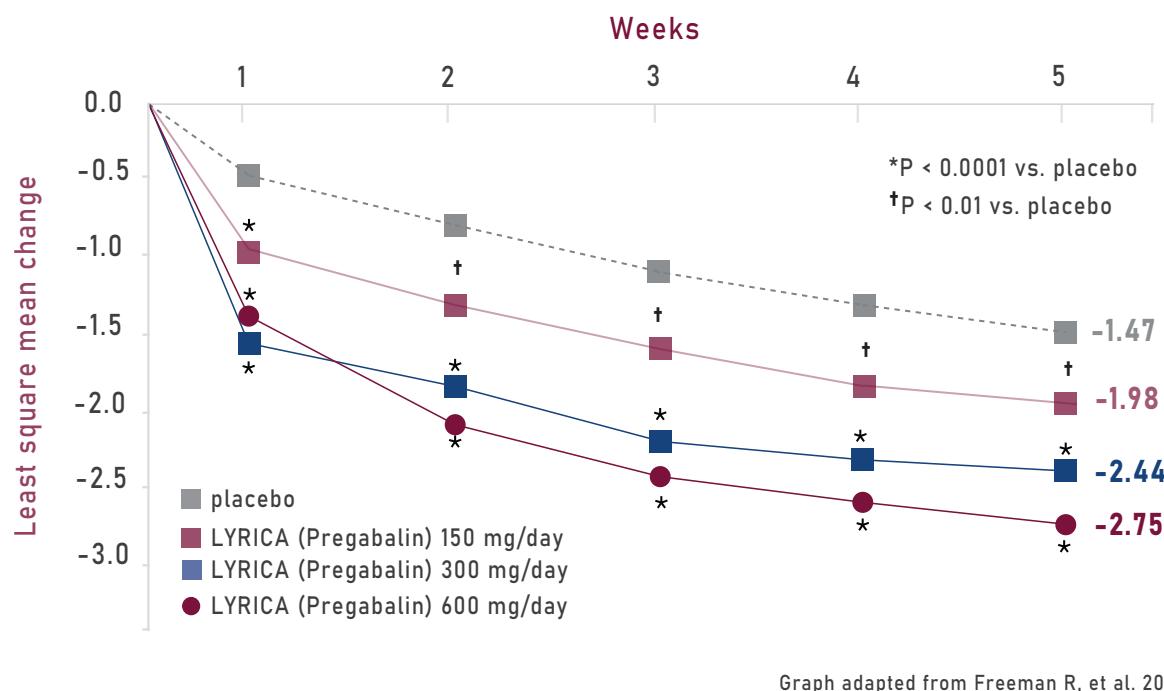




LYRICA® provides superior efficacy for the management of neuropathic pain (pDPN)¹



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



Pregabalin in diabetic peripheral neuropathy. This data were pooled across seven double-blind, randomised, placebo-controlled trials in painful DPN. Patients received Pregabalin (LYRICA®) 150–600 mg/day BID or TID, according to treatment response and tolerability. Reductions of least square mean change were observed for all three dosages investigated: -1.98, -2.44, and -2.75 points for patients receiving pregabalin 150, 300, and 600 mg/day vs. -1.47 for patients receiving placebo (*P<0.0001 vs. placebo; †P<0.01 vs. placebo).

BID: Twice daily. TID: Three times daily. pDPN: painful Diabetic Peripheral Neuropathy.

Reference 1: Freeman R, et al. Efficacy, safety, and tolerability of pregabalin treatment for painful diabetic peripheral neuropathy: findings from seven randomized, controlled trials across a range of doses. Diabetes Care. 2008;31(7):1448–54.

LYRICA® provides fast pain relief as early as week 1¹

LYRICA® was shown to significantly reduce neuropathic pain associated with DPN¹

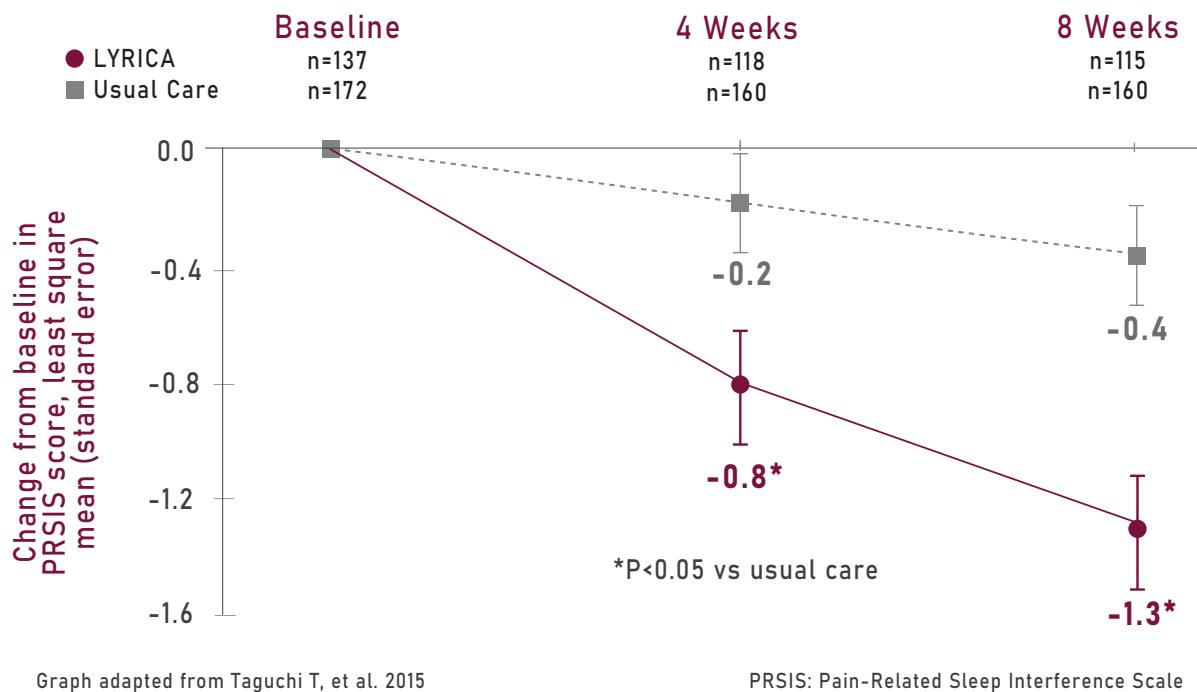
The result demonstrated a consistent pain reduction in all the LYRICA® dosages¹



LYRICA® improves patient sleep and quality of life¹



Change from baseline in sleep disturbance, assessed using the PRSIS



Pregabalin versus usual care for neuropathic chronic low back pain. This prospective, non-interventional, observational study enrolled Japanese adults (>18 years) with CLBP-NeP of duration ≥ 3 months and severity ≥ 5 on a numerical rating scale (0=no pain, 10=worst possible pain). Treatment was 8 weeks with pregabalin (n=157) or usual care alone (n=174); choice of treatment was determined by the physician. In clinical practice in patients with CLBP-NeP, pregabalin showed significantly greater improvements in pain-related interference with sleep relative to usual care.

Patients experienced significant reduction in pain-related sleep interference¹

The LYRICA® group had significant and sustained pain relief up to 8 weeks of treatment as compared to usual care in CLBP-NeP patients (p<0.05)¹

Study design: A prospective, non-interventional, observational study of Japanese adults (≥ 18 years) with chronic Low Back Pain with a neuropathic component for three or more months and severity ≥ 5 on a numerical rating scale (NRS) (0=no pain, 10=worst possible pain). Treatment was eight weeks with LYRICA® (flexible dose, 25-300 mg/day, n=157) or usual care alone (n=174). Choice of treatment was determined by the physician. The primary objective was to evaluate the impact of LYRICA® on sleep, pain, function, and health status in people with chronic Low Back Pain with a neuropathic component under routine clinical practice. Significance was declared if the 2-tailed test for the difference between treatment groups was significant at the 0.05 level. The primary efficacy outcome was change from baseline to 8 weeks in pain-related interference with sleep, assessed using the Pain-Related Sleep Interference Scale (PRSIS; 0=did not interfere with sleep, 10=completely interferes with sleep).

CLBP-NeP: Chronic low back pain with neuropathic component

Reference 1: Taguchi T, et al. Effectiveness of pregabalin for the treatment of chronic low back pain with accompanying lower limb pain (neuropathic component): a non-interventional study in Japan. J Pain Res. 2015;8:487-97.



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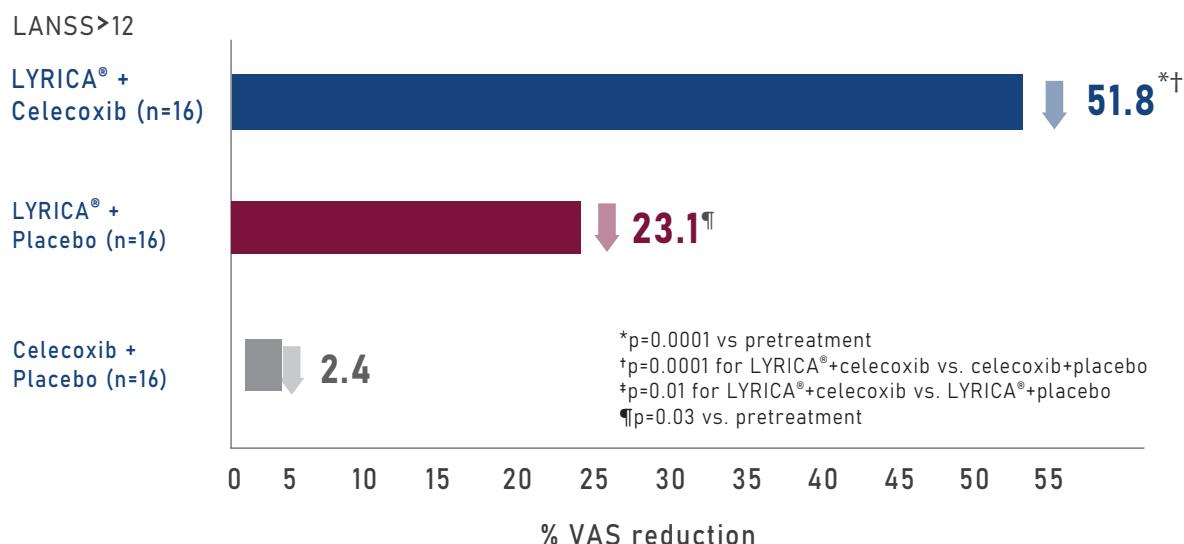
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PREGABALIN



LYRICA® significantly reduces chronic low back pain with a neuropathic component¹



Mean pain reduction (VAS) at the end of treatment with LYRICA®, celecoxib and their combination¹



Graph adapted from ROMANO et al., 2009

LANSS pain scale used to assess whether pain is predominately neuropathic in origin. Patients with a LANSS score ≥12 indicates neuropathic mechanisms are likely to be contributing to the patient's pain.

CLBP:Chronic Low Back Pain, LANSS:Leeds Assessment of Neuropathic Symptoms and Signs, NeP: Neuropathic Pain, VAS: Visual Analog Pain Scale.
Reference 1: Romano CL, et al. Pregabalin, celecoxib, and their combination for treatment of chronic low back pain. J Orthop Traumatol. 2009;10(4):185-91

Combination therapy is more effective than monotherapy¹

LYRICA® + Celecoxib provides 51.8% significant pain improvement in CLBP-NeP patients.

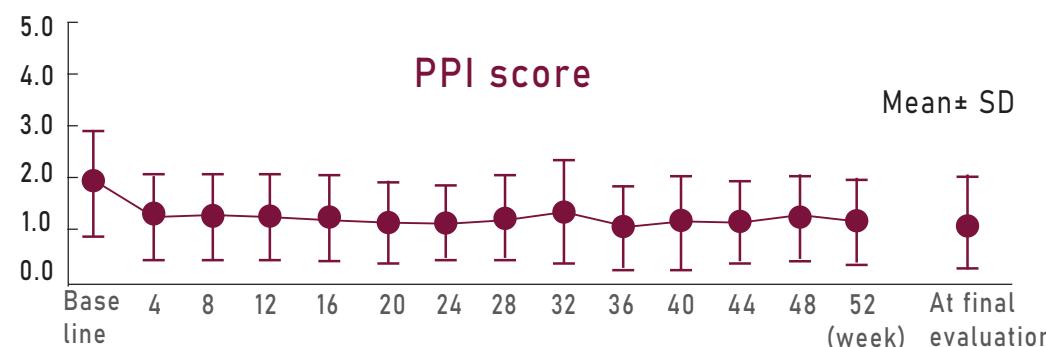
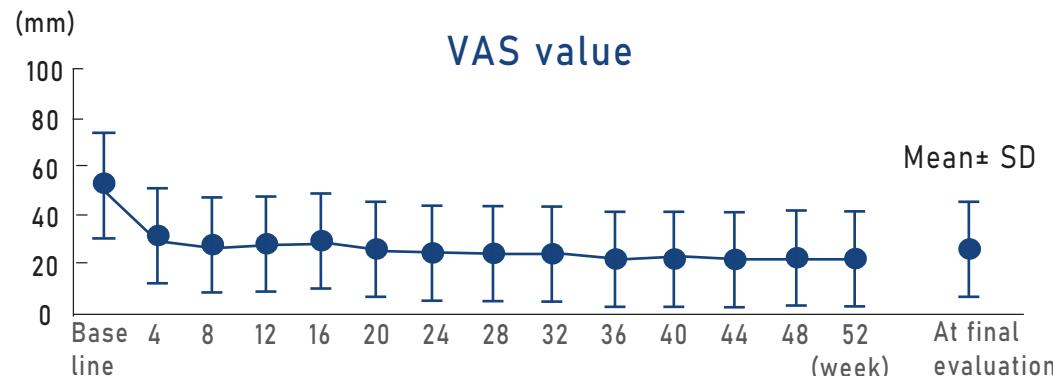
Less improvement was observed with monotherapy (LYRICA® or Celecoxib alone)

LYRICA® addresses the neuropathic component of low back pain. Celecoxib addresses the nociceptive component of chronic low back pain

Study design: A prospective randomized trial. 36 patients received three consecutive 4-week treatment regimens, randomly assigned: celecoxib plus placebo, LYRICA plus placebo, and celecoxib plus LYRICA. All patients were assessed by using a VAS (0-100 mm) and the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale by an investigator blinded to the administered pharmacological treatment. Primary outcomes were mean pain reduction following different treatment regimens. A Student's t-test was used for statistical analysis. Statistical significance was defined as P<0.05.



LYRICA® provides favourable long-term safety and tolerability¹



Graph adapted from Satoh J, et al.; 2011

The subjects received pregabalin 150–600 mg/day, 52 weeks, open label.

VAS: Visual analog scale, PPI: Present pain intensity. SD: Standard deviation

References:

1. Satoh J, et al. Efficacy and safety evaluation of pregabalin treatment over 52 weeks in patients with diabetic neuropathic pain extended after a double-blind placebo-controlled trial. *J Diabetes Investig.* 2011;2(6):457-63.
2. Toth C. Pregabalin: latest safety evidence and clinical implications for the management of neuropathic pain. *Ther Adv Drug Saf.* 2014;5(1):38-56.

LYRICA® has proven beneficial for pain relief with analgesic effects over the period of 52 weeks¹

No new concerns about safety as a result of long-term administration of LYRICA®¹

Manageable adverse events, mostly mild to moderate and transient^{1,2}



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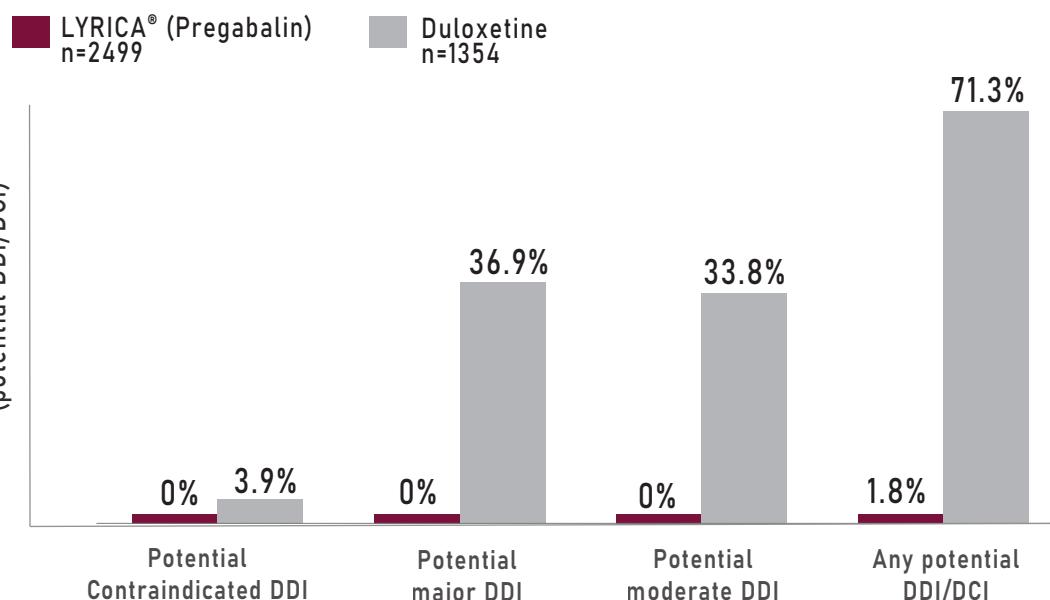
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LYRICA® has shown a lower drug-drug interactions as compared to Duloxetine¹



Frequency of potential DDIs and DCIs in patients with DPN¹
Pregabalin vs Duloxetine



Graph adapted from Johnston JJ, et al; 2013

LYRICA® is suitable for patients taking multiple medications with comorbidities¹

The study showed Duloxetine has higher potential DDIs and DCIs as compared to LYRICA®¹

An increased DDIs and DCIs was associated with increased health care costs in Duloxetine users¹

DDIs: drug-drug interactions; DCIs: drug-condition interactions; DPN: diabetic peripheral neuropathy

Reference: 1. Johnston SS, et al. Cost comparison of drug-drug and drug-condition interactions in patients with painful diabetic peripheral neuropathy treated with pregabalin versus duloxetine. Am J Health-Syst Pharm. 2013.



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Pregabalin (LYRICA®) is recommended as 1st line treatment in multiple guidelines¹⁻⁹



Pregabalin (LYRICA®) is recommended as 1st line treatment option for neuropathic pain and the only Level-A evidence for painful diabetic neuropathy³



(EFNS) The European Federation of Neurological Societies 2010¹

(IASP) The International Association for the Study of Pain 2010²

Pregabalin (LYRICA®) is recommended as first-line for the treatment of:

- Diabetic neuropathic pain (*Level A rating for efficacy*)
- Postherpetic neuralgia (*Level A rating for efficacy*)
- Central neuropathic pain caused by stroke, spinal cord injury or multiple sclerosis (*Level A rating for efficacy in spinal cord injury*)



(AAN) The American Academy of Neurology 2011³

Pregabalin (LYRICA®) is recommended as *the only management option with Level A evidence* for painful diabetic peripheral neuropathy (pDPN)



- Neuropathic Pain Special Interest Group (NeuPSIG) of IASP 2015⁴

- The Canadian Pain Society (CPS) 2014⁵

- The Korean Society of Spine Surgery 2011⁶

- The National Institute for Health and Care Excellence (NICE) Guidelines for England and Wales 2013^{9*}



Pregabalin (LYRICA®) is recommended as first-line for the management of neuropathic pain.



*Except trigeminal neuralgia.



(MASP) The Malaysian Association for the Study of Pain Guidelines on the management of neuropathic pain 2012⁷

Pregabalin (LYRICA®) is recommended as first-line for the management of:

- Painful diabetic peripheral neuropathy
- Postherpetic neuralgia



(RACGP) The Royal Australian College of General Practitioners 2013⁸

Pregabalin (LYRICA®) is recommended as first-line for the management:
- painful diabetic polyneuropathy

References:

1. Attal N, et al. EFNS Guidelines on the Pharmacological Treatment of Neuropathic Pain: 2010 Revision. Eur J Neurol. 2010;17(9):1113-88.
2. Ballantyne J, et al. Pharmacological Management of Neuropathic Pain. International Association Study of Pain. 2010;18(9):1-8.
3. Bril V, et al. Evidence-based guideline: Treatment of painful diabetic neuropathy: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. Neurology. 2011;76(20):1758-65
4. Finnerup NB, et al. Pharmacotherapy for Neuropathic Pain in Adults: A Systematic Review and Meta-Analysis. Lancet Neurol. 2015;14(2):162-73.
5. Moulin D, et al. Pharmacological Management of Chronic Neuropathic Pain: Revised Consensus Statement from the Canadian Pain Society. Pain Res Manag. 2014;19(6):328-35.
6. Chung KJ, et al. A Treatment Guideline for Neuropathic Pain. J Korean Soc Spine Surg. 2011;18(4):246-353.
7. Vijayan R, et al. Management of Neuropathic Pain. Malaysian Assoc Study Pain. 2012;1-36.
8. Votrubec M, et al. Neuropathic Pain. A Management Update. Aust Fam Physician. 2013;42(3):92-7.
9. Longson D, et al. The Pharmacological Management of Neuropathic Pain in Adults in Non-Specialist Settings. National Institute for Health and Care Excellence. 2013;173



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LYRICA® provides favourable pharmacokinetic profile^{1,2}



Easy to use in clinical practice^{1,2}

Oral bioavailability	≥90% (dose-independent) ^{1,2}
Pharmacokinetic Profile	Predictable with linear absorption across the therapeutic dose range. ^{1,2}
Dosing	BD or TDS ²
Drug drug interactions	Unlikely to produce or be subject to pharmacokinetic interactions ^{1,2}
Hepatic metabolism	Pregabalin (LYRICA®) does not bind to plasma proteins and is excreted virtually unchanged (<2% metabolism) by the kidneys ^{1,2}
Renal elimination	Can be administered in patients with renal impairment (adjusting dose to renal function) ^{1,2}

No interactions likely on people already taking commonly prescribed drugs, e.g. those taking oral antidiabetics, diuretics, insulin, phenobarbital, tiagabine and topiramate²

BD: Twice a day. TDS: Three times a day

References: 1. Ben-Menachem E. Pregabalin Pharmacology and Its Relevance to Clinical Practice. Epilepsia. 2004;45(Suppl 6):13-18. 2. Malaysia LYRICA® Prescribing Information.



LYRICA® is convenient, flexible with simple dosage regimen²



NeP and pDPN are chronic conditions¹.

It is important to remain on therapy to ensure adequate pain relief.

Recommended Dosing - Neuropathic Pain²

Starting Dose

If needed, after
3 - 7 days
interval

If needed, after additional
7 days
interval

150 mg/day

300 mg/day

600 mg/day



75 mg BD

or



50 mg TDS

150 mg BD

Maximum
600 mg daily

Capsules are not shown in scale

The greatest effect of pain relief was observed in patients treated
with pregabalin (LYRICA®) 600 mg/day³.

Lyrica® easy to take² :

- Simple twice-daily dosing
- Can be taken with or without food
- Dose may be tailored to individual response to Lyrica®



BD: Twice a day. TDS: Three times a day. pDPN: painful Diabetic Peripheral Neuropathy. NeP: Neuropathic Pain

References: 1. Johnston SS, et al. Cost comparison of drug-drug and drug-condition interactions in patients with painful diabetic peripheral neuropathy treated with pregabalin versus duloxetine. Am J Health-Syst Pharm. 2013.

2. Malaysia LYRICA® Prescribing Information.

3. Freeman R, et al. Efficacy, safety, and tolerability of pregabalin treatment for painful diabetic peripheral neuropathy: findings from seven randomized, controlled trials across a range of doses. Diabetes Care. 2008;31(7):1448-54.



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Choose LYRICA® for the treatment of Neuropathic Pain



FAST RELIEF
of neuropathic pain symptoms¹



Significantly reduced
SLEEP DISTURBANCE²



WELL TOLERATED
with long term **SAFETY PROFILE**⁵



Low potential of pharmacokinetic
DRUG INTERACTIONS^{3,4}



COMBINATION THERAPY
(LYRICA® + Celecoxib) is **MORE EFFECTIVE**
for CLBP-NeP patient⁶



Scan here for LYRICA®
Abbreviated Prescribing Information



<http://viatrismyapi-lyrica.com>

References:

- Freeman R, et al. Efficacy, safety, and tolerability of pregabalin treatment for painful diabetic peripheral neuropathy: findings from seven randomized, controlled trials across a range of doses. *Diabetes Care.* 2008;31(7):1448-54.
- Taguchi T, et al. Effectiveness of pregabalin for the treatment of chronic low back pain with accompanying lower limb pain (neuropathic component): a non-interventional study in Japan. *J Pain Res.* 2015;8:487-97.
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CLBP-NeP: Chronic lower back pain with Neuropathic Pain

Full prescribing information available upon request.



Market Authorization Holder:

Viatris Sdn. Bhd.

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15-03 & 15-04, Level 15, Imazium, No. 8, Jalan SS 21/37, Damansara Uptown,
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