a nuvista pharma initiative

medevista

A selective, potent, safe & well tolerated analgesic for better management of diabetic peripheral neuropathic pain and post herpetic neuralgia in adults

mirotop®

Mirogabalin 5 & 10 mg Tablet

Selective. Potent. Well Tolerated

Drug Review

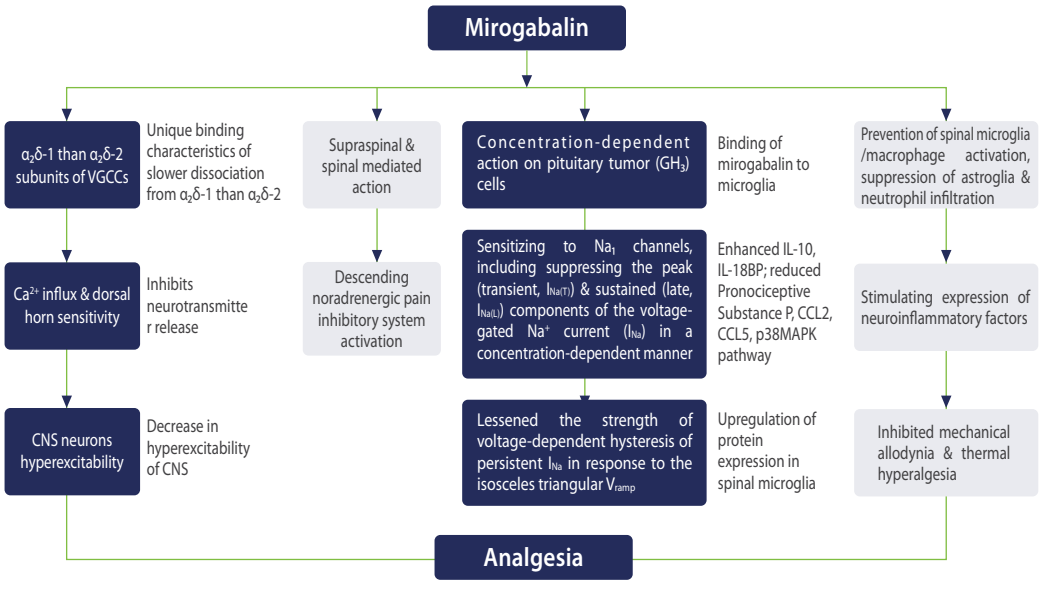
Peripheral neuropathic pain:

- Neuropathic pain (NeP) (central or peripheral) is defined by the International Association for the Study of Pain (IASP) as "pain caused by a lesion or disease of the somatosensory nervous system".[1]
- Peripheral neuropathic pain (PNP) in diabetic peripheral neuropathy (DPN) and post herpetic neuralgia (PHN) is a chronic and debilitating condition leading to significant morbidity and poor quality of life.[2]
- The prevalence of DPN is estimated at ~50% and expected to increase significantly over the next few decades.[3,4]
- After initial herpes zoster infection subsides, 6.5-18% of patients may develop PHN persists for months to years, significantly impacting quality of life.[5]
- An estimated 50% of patients with NeP achieve 30–50% pain relief due to suboptimal analgesia and poorly tolerated side effects.[6]
- Although pregabalin and gabapentin are effective in managing NeP, its tolerability limits their clinical utility in a substantial proportion of patients. Hence an effective and well-tolerated pharmacotherapy is required to address the concerns in managing NeP, especially in the gabapentinoid class.[7]

Mirogabalin: selective and well tolerated analgesic for DPNP and PHN[8]

- Mirogabalin besylate is a gabapentinoid approved for diabetic neuropathic pain and post-herpetic neuralgia.
- It has a potent pain-modulating effect with a unique, selective, high affinity and prolonged dissociation rate for the α2δ-1 subunit of voltage-gated calcium (Ca2+) channels (VGCCs) on the dorsal root ganglion resulting in more sustained analgesia compared with traditional gabapentinoids.
- Additionally, mirogabalin has a superior adverse events (AEs) profile due to a rapid dissociation from the α2δ-2 subunit of VGCCs potentially implicated in central nervous system specific AEs.

Mirogabalin: Analgesic mechanism[9]



Mirogabalin vs Pregabalin and Gabapentin in peripheral neuropathic pain[10]

Feature	Mirogabalin	Pregabalin	Gabapentin
Binding Affinity	Stronger binding to $\alpha_2\delta_1$ & $\alpha_2\delta_2$	Non-selective binding to $\alpha_2\delta_1$ & $\alpha_2\delta_2$	Non-selective binding to $\alpha_2\delta_1$ & $\alpha_2\delta_2$
Dissociation Rate	Slower from $\alpha_2\delta_1$ subunit	Faster dissociation	Faster dissociation
Efficacy	Higher analgesic efficacy	Moderate efficacy	Moderate efficacy
Adverse Effects	Lower incidence of CNS adverse effects	Higher incidence of CNS adverse effects	Higher incidence of CNS adverse effects
Common Side Effects	Dizziness, somnolence, headache	Higher incidence of Dizziness, somnolence, headache	Higher incidence of Dizziness, somnolence, headache
Long-term Tolerability	Well tolerated with minimal safety concerns	Associated with higher adverse effect	Associated with higher adverse effects
Onset of action	Maximum plasma concentration is achieved in less than 1 hour	Maximum plasma concentration is achived in 1 hour	Maximum plasma concentration is achieved in 3 hours

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Selective. Potent. Well Tolerated

Mirogabalin shows greater sustained analgesia due to a high affinity to, and slow dissociation from, the **α2δ-1 subunits** than Pregabalin, in the dorsal root ganglion (DRG), which also responsible for least ADRs than Pregabalin

Rapid onset
Less than **1 hour**

More potent
17-fold more potent than pregabalin (300 mg)

Well Tolerated
52 weeks with mild to moderate ADRs

...ensures active life with quick & sustained relief from neuropathic pain

Ref.: 1. Tetsunaga et al. Journal of Orthopaedic Surgery and Research (2020) 15:191. **2.** Guo, X., Yu, Y., Zhang, Y. et al. A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled 14-Week Study of Mirogabalin in Chinese Patients with Diabetic Peripheral Neuropathic Pain. Pain Ther 13, 937–952 (2024).; **3.** National Guideline on Diabetes Mellitus, Chapter1, page.; **4.** Journal of Pain Research 2018:11 1559–1566.; **5.** Klompas, M., Kulldorff, M., Vilk, Y., Bialek, S.R., Harpaz, R. Herpes zoster and postherpetic neuralgia surveillance using structured electronic data. Mayo Clin Proc 2011, 86(12): 1146-53.; **6.** Finnerup, N.B.; Haroutounian, S.; Kamerman, P.; Baron, R.; Bennett, D.L.; Bouhassira, D.; Cruccu, G.; Freeman, R.; Hansson, P.; Nurmikko, T.; et al. Neuropathic pain: An updated grading system for research and clinical practice. Pain 2016, 157, 1599–1606.; **7.** Domon, Y., Arakawa, N., Inoue, T. et al. Binding characteristics and analgesic effects of mirogabalin, a novel ligand for the α2δ subunit of voltage-gated calcium channels. J Pharmacol Exp Ther 2018, 365(3): 573-82.; **8.** Burgess J, Javed S, Frank B, Malik RA, Alam U. Mirogabalin besylate in the treatment of neuropathic pain. Drugs Today (Barc). 2020 Feb;56(2):135-149.; **9.** Yang F, Wang Y, Zhang M and Yu S (2024) Mirogabalin as a novel calcium channel α2δ ligand for the treatment of neuropathic pain: a review of clinical update. Front. Pharmacol. 15:1491570.; **10.** Korean J Pain 2021;34(1):4-18 pISSN 2005-9159 eISSN 2093-0569.

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