

Enlyte

FDA Approves Combination NSAID/Opioid Seglentis

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On October 18, 2021, Seglentis was approved by the U.S. Food and Drug Administration (FDA). Seglentis contains tramadol, a short-acting opioid, and celecoxib, a non-steroidal anti-inflammatory drug (NSAID), and is indicated for adults in the management of acute pain that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Seglentis was approved as a tablet formulation containing 56mg of celecoxib and 44mg of tramadol. Currently, both medications are available generically in 100 or 200mg capsules for celecoxib and 50 or 100mg tablets for short-acting tramadol. This is important to note because the recommended initial treatment of Seglentis is two tablets every 12 hours as needed for pain relief, which is similar to readily available generic versions of the individual medications.

It should also be noted that this medication will require a Risk Evaluation and Mitigation Strategy (REMS) due to the risks for addiction, abuse, and misuse with opioids, even at recommended doses. Moreover, patients should be monitored for respiratory depression and prescribers should discuss naloxone (Narcan) for those at risk of overdose.

Impact on Workers' Compensation

Pain treatment, especially with NSAIDs and opioids, represents a large volume of active prescriptions for injured workers. Mitchell Pharmacy Solutions will continue to monitor and provide any relevant updates.

For more information or questions, please contact your client services manager or <u>view the FDA approval online</u>



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