

## Immediate Release: First Generics of Lyrica® Approved

On July 19, 2019, the U.S. Food and Drug Administration (FDA) approved the first generics of Lyrica (pregabalin). Lyrica is used to treat a variety of conditions including management of neuropathic pain linked to diabetic peripheral neuropathy and neuropathic pain associated with spinal cord injuries, management of postherpetic neuralgia, adjunctive treatment of partial onset seizures in patients age 17 years and older, and management of fibromyalgia.

Approvals were granted to the following manufacturers: Alembic Pharmaceuticals, Alkem Laboratories, Amneal Pharmaceuticals, Dr. Reddy's Laboratories, InvaGen Pharmaceuticals, MSN Laboratories, Rising Pharmaceuticals, Sciegen Pharmaceuticals and Teva Pharmaceuticals.

Pregabalin has a Schedule V controlled substance classification due to the potential for abuse and dependence. It must be dispensed with a patient Medication Guide listing the possible side effects and how to properly use the medication. Warnings for pregabalin include:

- ▶ Risk of angioedema or swelling of head, neck and throat
- ▶ Hypersensitivity reactions such as hives, difficulty breathing and wheezing
- ▶ Increased seizure frequency may occur along with other adverse effects if the drug is abruptly discontinued
- ▶ Increased risk of suicidal thoughts and behaviors
- ▶ Possible cause of peripheral edema or swelling of hands and legs, so caution should be taken when administering thiazolidinedione antidiabetic agents such as Actos (pioglitazone) or Avandia (rosiglitazone) at the same time
- ▶ May impair ability to drive and operate machinery due to the potential for causing dizziness and drowsiness

There were nine generics of pregabalin approved by the FDA at one time, which is unusual, creating competition and a significantly lower price than Lyrica. In most cases, a generic drug from one manufacturer is approved and granted six months of "generic exclusivity" before others can enter the market. During the exclusivity period, the price is typically only about 10% less than the brand medication. Once other generics are available, the price drops significantly.

Since pregabalin (Lyrica) is a widely used medication, the generic approvals will allow greater access and affordability to patients across the United States. For additional details, please view the FDA's [press release](#) or [Drugs@FDA](#) for pregabalin.

## References

1. FDA approves first generics of Lyrica. FDA News Release. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-generics-lyrica>. Updated July 22, 2019. Accessed July 25, 2019.
2. Cassels, C. FDA Approves First Lyrica Generics. Medscape Medical News. Available at: <https://www.medscape.com/viewarticle/915877>. Published July 22, 2019. Accessed July 25, 2019.

