



Exservan[®] (riluzole) – New orphan drug approval

- On November 22, 2019, the [FDA approved](#) Aquestive Therapeutics' [Exservan \(riluzole\)](#) oral film, for the treatment of amyotrophic lateral sclerosis (ALS).
- Riluzole is available generically as an [oral tablet](#) and as a brand oral suspension ([Tiglutik[™]](#)). These formulations are also approved for ALS.
- The efficacy of Exservan is based upon relative bioavailability and food-effect study in healthy subjects comparing oral riluzole tablets to Exservan oral film.
- Warnings and precautions for Exservan include hepatic injury, neutropenia, and interstitial lung disease.
- The most common adverse reactions ($\geq 5\%$ and greater than placebo) with riluzole use were oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain.
- The recommended dose of Exservan is 50 mg taken orally twice daily. Exservan should be taken at least 1 hour before or 2 hours after a meal.
 - Exservan should be applied on top of the tongue where it adheres and dissolves.
- Aquestive Therapeutics' launch plans for Exservan are pending. Exservan will be available as a 50 mg orally dissolving film.



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