

Supplemental Approvals

Generic Name (Trade Name—Company)

September 11, 2018

Riluzole oral suspension

(Tiglutik—ITF Pharma)

First easy-to-swallow riluzole liquid approved for treatment of ALS

Uses/Notes

FDA has [approved](#) riluzole oral suspension for the treatment of amyotrophic lateral sclerosis (ALS). It is the first and only easy-to-swallow thickened riluzole liquid for ALS and is administered twice daily via an oral syringe.

Approval was based on bioavailability studies comparing oral riluzole tablets to riluzole oral suspension. While riluzole's mechanism of action is not fully understood, in clinical studies it has been shown repeatedly to modulate glutamate neurotransmission by inhibiting both glutamate release and postsynaptic glutamate receptor signaling.

The most common adverse effects of the oral suspension are consistent with the established clinical profile of riluzole and include oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain.

Riluzole oral suspension has received orphan drug designation from FDA. The product will be available in mid-October.

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