



Approximately **85%** of all patients with ALS develop dysphagia¹

TIGLUTIK[®] (riluzole) is the only formulation of riluzole indicated for both oral and PEG tube administration

- Indicated throughout all stages of ALS²
- Administered twice daily and is bioequivalent to Rilutek[®] (riluzole) tablets²⁻⁴
- Easy-to-swallow oral suspension formulation

TIGLUTIK Was Formulated to Help Reduce Problems with Swallowing Riluzole Tablets

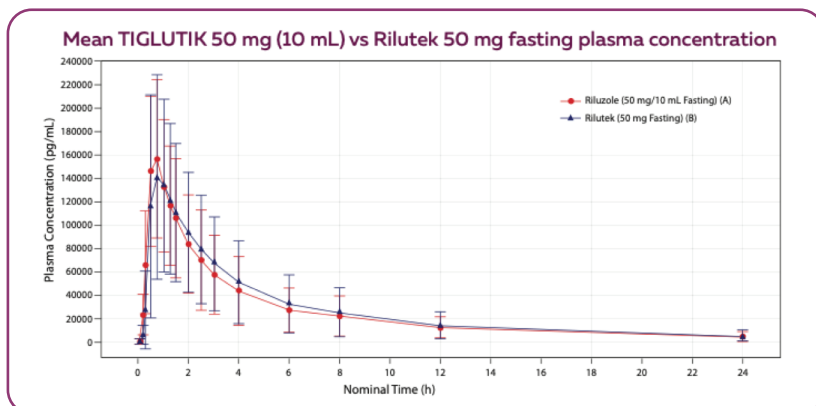
Crushing riluzole tablets could impair the swallowing ability in patients with ALS and increase the risk of aspiration⁵

TIGLUTIK oral suspension:

- Viscosity 300 times higher than water⁴
- Mildly thick consistency – IDDSI criterial Level 2 – based on the *International Dysphagia Diet Standardization Initiative* (IDDSI)^{4,6}
- Designed for ALS patients with dysphagia



TIGLUTIK Oral Suspension 50 mg (10 mL) is Bioequivalent to Rilutek 50 mg Tablets



Indication

TIGLUTIK[®] (riluzole) is indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS).

Important Safety Information

Contraindication

TIGLUTIK is contraindicated in patients with a history of severe hypersensitivity reactions to riluzole or to any of its components.

Please see Important Safety Information throughout and accompanying Full Prescribing Information



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Warnings and Precautions

TIGLUTIK can cause liver injury and there have been cases of drug-induced liver injury, some of which were fatal, in patients taking riluzole. Asymptomatic elevations of hepatic transaminases have been reported and, in some patients, have recurred upon re-challenge with riluzole. Maximum increases in ALT occurred within 3 months after starting riluzole. Monitor patients for hepatic injury every month for the first 3 months of treatment, and periodically thereafter; TIGLUTIK should be discontinued if there is evidence of liver dysfunction, for example, elevated bilirubin. Use of TIGLUTIK with other hepatotoxic drugs may increase the risk for hepatotoxicity.

TIGLUTIK can cause neutropenia. Cases of severe neutropenia (absolute neutrophil count less than 500 per mm³) within the first 2 months of riluzole treatment have been reported. Advise patients to report febrile illnesses.

TIGLUTIK can cause interstitial lung disease, including hypersensitivity pneumonitis. Discontinue TIGLUTIK immediately if interstitial lung disease develops.

Adverse Reactions

The most common adverse reactions (incidence greater than or equal to 5% and greater than placebo) of TIGLUTIK were oral hypoesthesia (29%), asthenia (19%), nausea (16%), decreased lung function (10%), hypertension (5%), and abdominal pain (5%).

Coadministration of TIGLUTIK with strong or moderate CYP1A2 inhibitors, such as ciprofloxacin, enoxacin, fluvoxamine, methoxsalen, mexiletine, oral contraceptives, thiabendazole, vemurafenib, and zileuton, may increase the risk of TIGLUTIK-associated adverse reactions.

Coadministration of TIGLUTIK with CYP1A2 inducers may result in decreased efficacy of TIGLUTIK.

Use in Specific Populations

Patients with mild or moderate hepatic impairment (Child-Pugh's score A or B) had increases in AUC compared to patients with normal hepatic function. Thus, patients with mild or moderate hepatic impairment may be at increased risk of adverse reactions. Use of TIGLUTIK is not recommended in patients with baseline elevations of serum aminotransferases greater than 5 times the upper limit of normal or evidence of liver dysfunction.

Japanese patients are more likely to have higher riluzole concentrations, and thus may be at a greater risk of adverse reactions.

Please see accompanying Full Prescribing Information.

REFERENCES

1. Onesti E, et al. Dysphagia in amyotrophic lateral sclerosis: impact on patient behavior, diet adaptation, and riluzole management. *Front Neurol.* 2017;8:94.
2. TIGLUTIK[®] (riluzole) [package insert]. Berwyn, PA: ITF Pharma; March 2020.
3. Rilutek (riluzole) [package insert]. Cary, NC: Covis Pharmaceuticals, Inc.; July 2016.
4. Data on file. ITF Pharma. Berwyn, PA; December 2019.
5. Keating GM. Riluzole oral suspension in amyotrophic lateral sclerosis: a guide to its use. *Drugs Ther Perspect.* 2016;32(7):282-286.
6. International Dysphagia Diet Standardisation Initiative. <https://iddsi.org/>. Accessed June 24, 2020.



How to Order TIGLUTIK

To help make the TIGLUTIK[®] (riluzole) prescribing process as easy as possible, TIGLUTIK is only available through Anovo Specialty Pharmacy.

Prescribing TIGLUTIK

Prescribing TIGLUTIK is designed to be easy and can be done via:



Phone: (844) 763-1198



Fax: (855) 813-2039



E-scribe—Follow these 3 steps:

1. Search for Anovo in your EHR system
2. Select [AnovoRxPharmacy#5](#)
3. Remember the Anovo NABP/NCPDP Provider ID: [4445640](#)

- When ordering TIGLUTIK in an Electronic Health Record (EHR), and the TIGLUTIK name does not appear, simply contact Anovo at [\(844\) 763-1198](#) and they will help you complete the intake forms
- Anovo will engage with the patient's insurance company to help alleviate the burden on the prescriber's office. There may be situations where Anovo will have to follow up with the prescriber's office to request missing information
- Once all the paperwork is completed, Anovo will call the patient or his/her designee to confirm shipment of TIGLUTIK

Helping Patients Get Their Medication

Features of TIGLUTIK® (riluzole) support

- ITF Pharma is dedicated to working with prescribers so ordering TIGLUTIK is as easy as possible
- Patients eligible for copay support **pay no more than \$50** per filled prescription of TIGLUTIK*
- Ask your Specialty Account Manager about the ITF Pharma *Bridge Program* for patients with Medicare Part D insurance

*See Eligibility and Restrictions below.

Benefits of Anovo Specialty Pharmacy

- **Administrative support:** Anovo provides ongoing assistance to healthcare professionals and patients with expert handling of the necessary paperwork and insurance requirements
- **Direct-to-patient convenience:** TIGLUTIK is shipped from Anovo directly to your patient
- **Ongoing assistance:** Anovo will help alleviate the burden on the patients to remember their refills of TIGLUTIK and manage insurance and challenges with reimbursement
- **Comprehensive communication:** Knowledgeable and highly trained staff are available to answer any TIGLUTIK treatment-related questions
- **No questions left unanswered:** If you have any questions, you are encouraged to call Anovo at **(844) 763-1198** – they are there to help

Eligibility and Restrictions

Offer is valid for each prescription fill for commercially insured patients where TIGLUTIK is covered. Offer is valid for patients aged 18 and older. Medicare, Medicaid, TRICARE, or other patients of other federal or state programs are not eligible. ITF Pharma reserves the right to rescind, revoke, or amend this offer without notice. Offer good only in the USA, including Puerto Rico, at participating retail pharmacies. Void if prohibited by law, taxed, or restricted. This offer has no cash value and may not be used in combination with any other discount, coupon, rebate, free trial, or similar offer for the specified product. Maximum savings limit applies; patient out-of-pocket expense may vary.



Prescription Order Form

Fax to (855) 813-2039

Please call Anovo at (844) 763-1198 if you need assistance ordering TIGLUTIK

Patient Information:

Name _____ Male Female Date of Birth ____/____/____
Address _____ City _____ State _____ ZIP _____
Home Phone _____ Work Phone _____ Cell Phone _____
Emergency Contact _____ Phone _____ Relationship _____
Caregiver Name _____ Phone _____ Relationship _____

Permission for Anovo to talk to caregiver on behalf of patient Yes No

Insurance Information:

Please attach copy of front and back of Insurance Card(s)

Primary Insurance Co. Name _____ Insurance Phone # _____ Group # _____
Policy Holder Name _____ Policy Holder DOB _____ Policy # _____
Prescription Card Name _____

Prescription Information:

Drug: TIGLUTIK 50 mg/10 mL Oral Suspension (300 mL) NDC 70726-0303-2
Route of Administration: Oral PEG Tube
Directions: _____
Quantity: 600 mL (30-day supply) or _____ **Refill:** _____

Diagnosis/ICD-10 _____

Allergies _____

Prescriber Information:

Prescriber Signature _____ Date ____/____/____
Prescriber Name _____ Practice/Facility Name _____
Prescriber Specialty _____
Address _____ City _____ State _____ ZIP _____
Phone _____ Fax _____ Email Address _____
NPI # _____ Name of Contact Person _____ Contact Person #, ext or email _____

Web