Tiglutik®
riluzole
oral suspension
50 mg/10 mL (5 mg/mL)

Approximately 85% of all patients with ALS develop dysphagia[1]

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

- Indicated throughout all stages of ALS[2]
- Administered twice daily and is bioequivalent to Rilutek® (riluzole) tablets[2-4]
- Easy-to-swallow oral suspension formulation

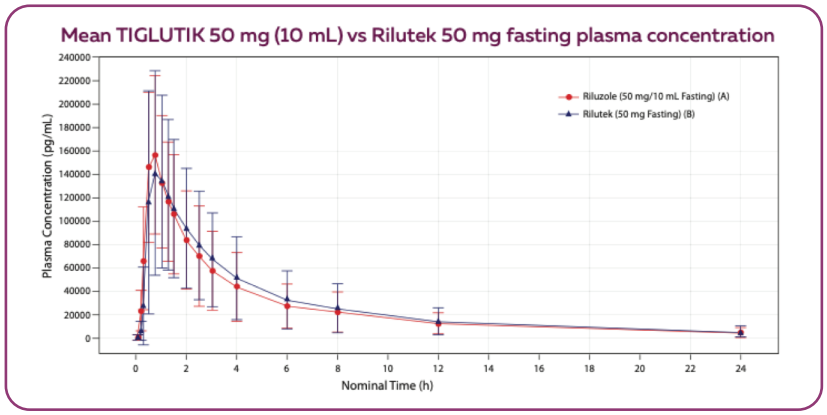
TIGLUTIK Was Formulated to Help Reduce Problems with Swallowing Riluzole Tablets

Crushing riluzole tablets could impair the swallowing ability in patients with ALS and increase the risk of aspiration[5]

TIGLUTIK oral suspension:

- Viscosity 300 times higher than water[4]
- 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.

ITF Pharma Corporate Office
850 Cassatt Road, Suite 350, Berwyn, PA 19312

ITF Pharma

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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.

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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_____

ALSNews

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