November 2025

IMPORTANT PRESCRIBING INFORMATION

Subject: Temporary importation of TEGLUTIK (riluzole oral suspension, 5 mg/mL) with English labeling to address drug shortage in the United States

Dear Health Care Provider,

The purpose of this letter is to inform you about a temporary importation in the United States (U.S.) of TEGLUTIK (riluzole 5 mg/mL oral suspension) with bottle and carton labels in English, in coordination with the U.S. Food and Drug Administration (FDA) to mitigate the current shortage of FDA-approved Tiglutik (riluzole oral suspension, 50 mg/10 mL) in the U.S. This temporary supply of TEGLUTIK is marketed and manufactured by Italfarmaco in Spain and is not FDA-approved.

Riluzole is indicated for the treatment of amyotrophic lateral sclerosis (ALS). Recently, Tiglutik was recalled in the U.S. market due to an out-of-specification test result for viscosity.

At this time, no other entity except EDW Pharma, Inc. (formerly Italfarmaco (ITF) Pharma, Inc.) is authorized by the FDA to import or distribute Italfarmaco's TEGLUTIK riluzole oral suspension in the U.S.

Effective immediately, and during this temporary period, EDW Pharma, Inc. will distribute the following presentation of riluzole oral suspension to address the critical shortage:

Product Name	Quantity	Description	U.S. NDC Number	Lot Number	Expiration Date
TEGLUTIK riluzole oral suspension (5 mg/mL)	1 bottle per carton	Teglutik is presented as a slightly brown, opaque homogeneous oral suspension after being manually gently shaken. TEGLUTIK is available in a bottle of 300 ml with a plastic graduated oral dosing syringe. The syringe barrel is graduated in milliliters up to 10 ml.	70726-0306-1	25014	06-2028

The safety profiles of the FDA-approved Tiglutik and imported TEGLUTIK products are comparable and no specific safety concerns emerged from the comparison of the two products.

Please refer to the side-by-side comparison of the labels (enclosed) for additional information.

Tiglutik is available only by prescription in the U.S. The imported lot does not have the statement "Rx only" on its labeling.

The barcode on the imported product label may not register accurately on the U.S. scanning systems. Institutions should manually input the imported product information into their systems and confirm that the barcode, if scanned, provides correct information. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

In addition, the package of the imported product does not include a product identifier as required under the Drug Supply Chain Security Act (DSCSA). Specifically, each package does not include the NDC, unique serial number, lot number, and expiration date in both human-readable and a two-dimensional data matrix barcode. Additionally, the imported product may not be accompanied with DSCSA-required product tracing documentation (transaction information, transaction history, and transaction statement).

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events and medication errors in patients taking TEGLUTIK to AnovoRx at 1-844-763-1198. You are encouraged to report negative side effects of prescription drugs to the FDA.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

You may also contact AnovoRx at 1-844-763-1198 if you have any questions about the information contained in this letter or the safe and effective use of TEGLUTIK.

This letter is not intended as a complete description of the benefits and risks related to the use of TEGLUTIK. Please refer to the enclosed TEGLUTIK SmPC and Tiglutik USPI side-by-side comparison.

For additional information, please visit www.tiglutik.com and www.edwpharma.com.

Sincerely,

Peter Cook
CEO and President
EDW Pharma, Inc. *(Formerly ITF Pharma, Inc.)*

Enclosures:
1 – TEGLUTIK and Tiglutik side-by-side comparison of the bottle and carton labels
2 – TEGLUTIK SmPC and Tiglutik USPI side-by-side comparison
3 – TEGLUTIK and Tiglutik side-by-side comparison of the patient leaflet