

TEGLUTIK- riluzole liquid
EDW PHARMA, INC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Important Prescribing Information

January 2024

Subject: Temporary importation of TEGLUTIK (riluzole oral suspension, 5 mg/mL) with non-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 Greek, 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 by Italfarmaco in Greece and manufactured 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	Descriptions	U.S. NDC number	Lot Number	Expiration Date
TEGLUTIK riluzole oral carton 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	70726-0304- 1	23023	11-26

syringe. The syringe barrel is graduated in milliliters up to 10 ml.

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.

It is important to note that the enclosed side-by-side comparisons, in English, between the U.S. product information and the European product information including the labels, patient leaflet, and SmPC (Summary of Product Characteristics, equivalent to the U.S. Prescribing Information (USPI)) have been included to also provide all applicable information since the labels and leaflet with the imported product are in Greek.

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 TIGLUTIK. Please refer to the enclosed TIGLUTIK 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.)



(ENGLISH TRANSLATION OF GREEK BOTTLE label - TEXT)

(u.s. BOTTLE label - TEXT)

NAME OF THE MEDICINAL PRODUCT
TEGLUTIK 5 mg/ml oral suspension
riluzole

NAME OF THE MEDICINAL PRODUCT
TIGLUTIK®
riluzole
oral suspension
50mg/10ml(5mg/ml)

STATEMENT OF ACTIVE SUBSTANCE(S)
1 ml contains: 5 mg of riluzole

STATEMENT OF ACTIVE SUBSTANCE(S)
Contains: TIGLUTIK® 50 mg/10 mL (5 mg/mL)

LIST OF EXCIPIENTS
Also contains: liquid sorbitol (E420)

PHARMACEUTICAL FORM AND CONTENTS
Oral suspension
Bottle of 300 ml

PHARMACEUTICAL FORM AND CONTENTS
s product is a ling Information.
TIGLUTIK® 50 mg/10 mL (5 mg/mL) oral suspension is a slightly brown, opaque, homogeneous suspension when mixed, containing 50 mg of riluzole per 10 mL of suspension

METHOD AND ROUTE(S) OF ADMINISTRATION
Read the package leaflet before use
Oral use

METHOD AND ROUTE(S) OF ADMINISTRATION
Before use, please read the enclosed Prescribing Information.
For oral administration
Shake gently before use

Administration via enteral feeding tubes

Shake gently before use

DOSAGE

SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

SPECIAL STORAGE CONDITIONS

Expiry:

Once opened, use within 15 days

GENERAL CLASSIFICATION FOR SUPPLY

Greece: Limited medical prescription from a specialist physician and monitoring during treatment.

Cyprus: Pharmaceutical product for which a medical prescription is required.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

ITF Hellas A.E.

Άρεως 103 & Αγίας Τριάδος 36,
17562 Παλαιό Φάληρο

Ελλάδα

Τηλέφωνο: +30 210 9373330

The bottle must be gently shaken for at least 30 seconds by continuously rotating the bottle 180° until the visual appearance of the suspension is homogeneous.

DOSAGE

The recommended dose is 10 mL of TIGLUTIK® oral suspension, containing 50 mg of riluzole, taken orally twice daily, every 12 hours.

SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of reach of children.

SPECIAL STORAGE CONDITIONS

Store TIGLUTIK® at controlled room temperature between 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) and protect from bright light.

Do not freeze. Store upright.

Once opened, the bottle of TIGLUTIK® should be used within 15 days. Keep bottle tightly closed between each use.

GENERAL CLASSIFICATION FOR SUPPLY

Rx only

ITF Pharma

Manufactured for:

ITF Pharma, Inc.

Berwyn, PA 19312 USA

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PRINCIPAL DISPLAY PANEL - 300 mL Bottle Carton



TEGLUTIK

riluzole liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70726-0304
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RILUZOLE (UNII: 7LJ087RS6F) (RILUZOLE - UNII:7LJ087RS6F)	RILUZOLE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SORBITOL (UNII: 506T60A25R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	brown (slightly brown, opaque)	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70726-0304-1	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/19/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		01/19/2024	

Labeler - EDW PHARMA, INC (080260470)

Registrant - EDW PHARMA, INC (080260470)

Revised: 2/2024

EDW PHARMA, INC