How to Use TIGLUTIK^{È} (riluzole) for PEG Tube Use

50 mg/10 mL oral suspension

Please review these instructions 'How to Use TIGLUTIK' before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

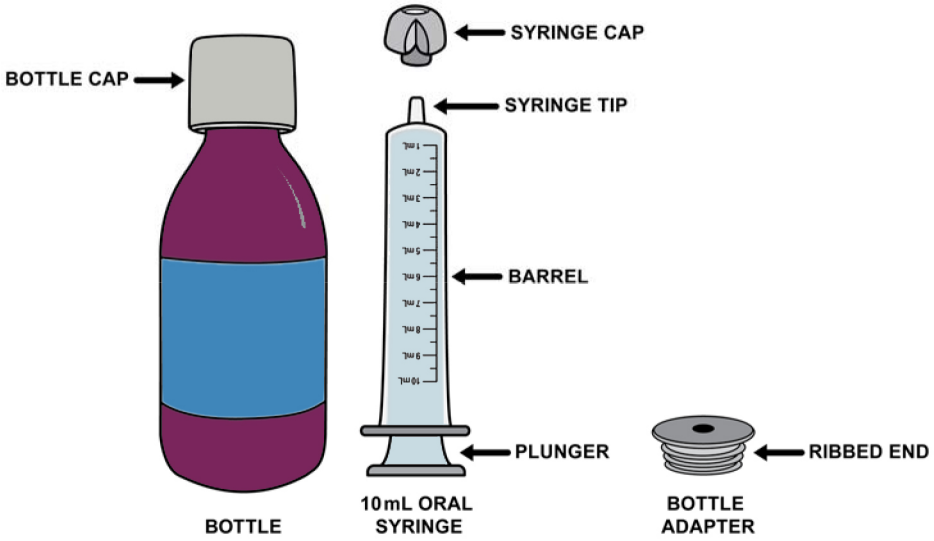
Important information about measuring TIGLUTIK:

Always use the oral syringe that comes with TIGLUTIK to measure your prescribed dose. Ask your healthcare provider or pharmacist to show you how to measure your prescribed dose.

Each TIGLUTIK carton contains:

- 2 TIGLUTIK bottles
- 2 bottle adapters
- 2 10 mL oral syringes
- 2 syringe tip caps

Use a new 10 mL oral syringe, bottle adapter, and syringe tip cap when using a new bottle of TIGLUTIK (see Figure A).



Important information:

- Keep these instructions for future use.
- Do not share TIGLUTIK with anyone else.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
- People who have problems using their hands may need assistance to draw up and give the correct dose of TIGLUTIK.

How to take TIGLUTIK:

- Take TIGLUTIK as prescribed by your healthcare provider. The recommended dose of TIGLUTIK is 50 mg (10 mL) 2 times each day, every 12 hours.
- TIGLUTIK can be taken by mouth or it can be given through a percutaneous endoscopic gastrostomy (PEG) tube. Both silicone and polyurethane PEG tubes can be used.
- Take TIGLUTIK at least 1 hour before or 2 hours after a meal.
- Take TIGLUTIK using a 10 mL oral syringe that comes with TIGLUTIK.

Step 1. **First time use of bottle only:** Remove one TIGLUTIK bottle, one bottle adapter, one 10 mL oral syringe, and one syringe tip cap from the carton (see Figure A).

Step 2. Gently shake the bottle **for at least 30 seconds** by continuously turning the bottle up and down until the TIGLUTIK suspension is mixed well and you do not see any clear liquid at the top of the suspension or any particles at the bottom of the bottle (see Figure B).

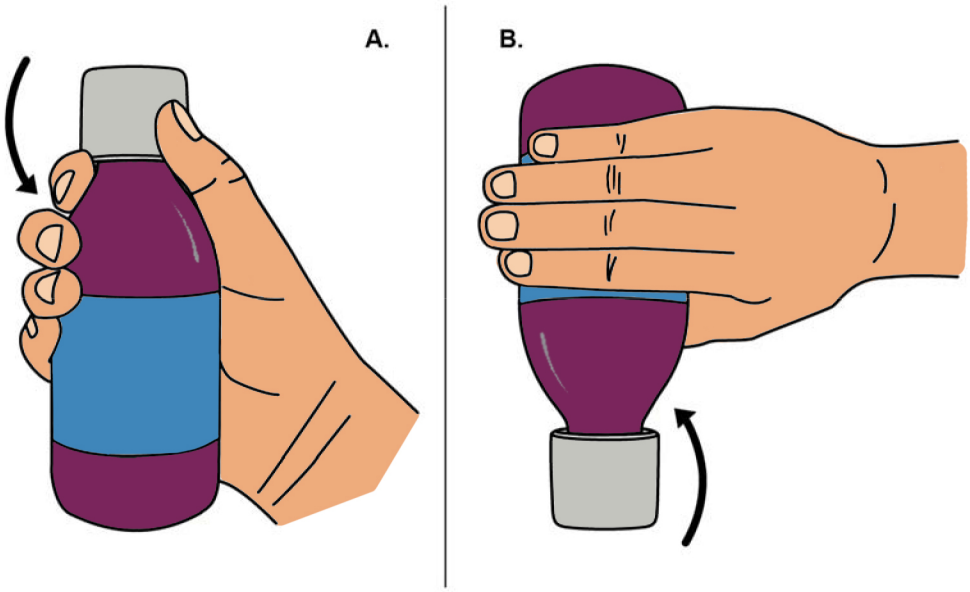


Figure B

Step 3. Open the bottle by pressing down on the bottle cap and turning it counterclockwise (to the left) (see Figure C).

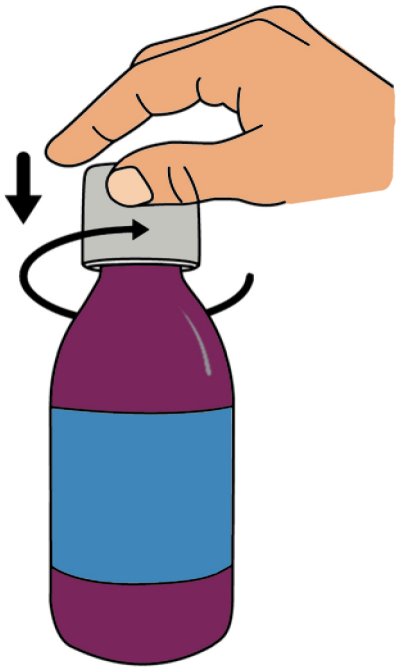


Figure C

Step 4. **First time use of bottle only:** Place the open bottle upright on a flat surface. Insert the ribbed end of the bottle adapter into the bottle by firmly pressing it in as far as it will go (see Figure D). **Do not** remove the bottle adapter from the bottle after it is inserted.

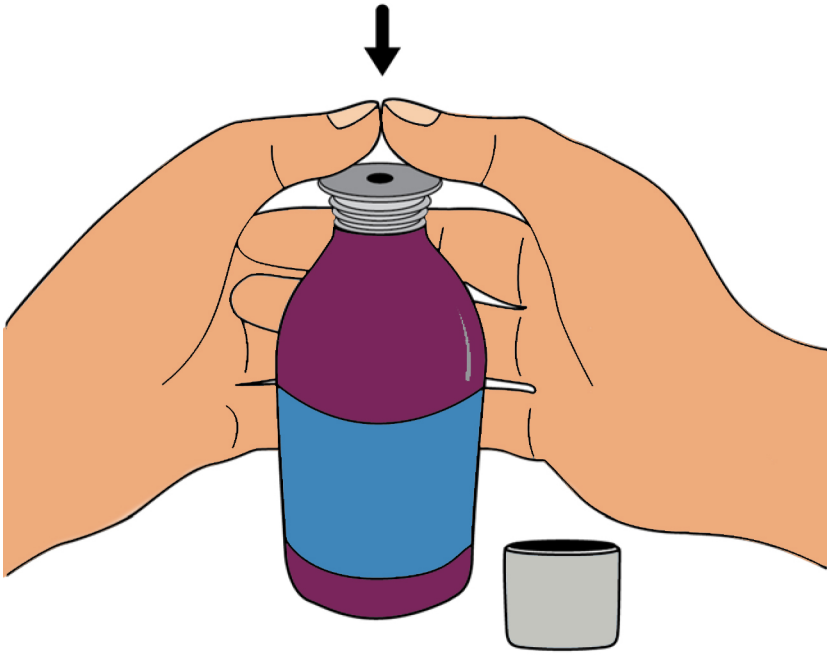


Figure D

Step 5. Push the plunger of the 10 mL oral syringe all the way in to remove air from the oral syringe (see Figure E).

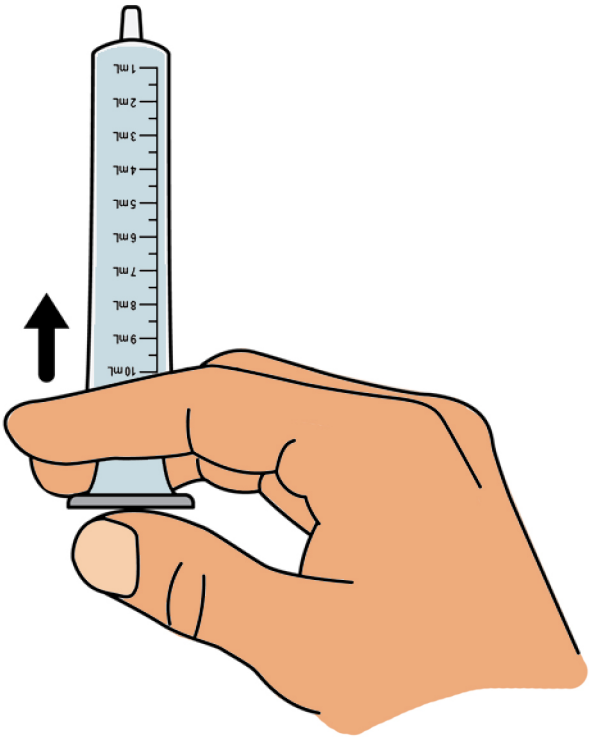


Figure E

Step 6. Insert the 10 mL oral syringe into the opening of the bottle adapter until the oral syringe is firmly in place (see Figure F).

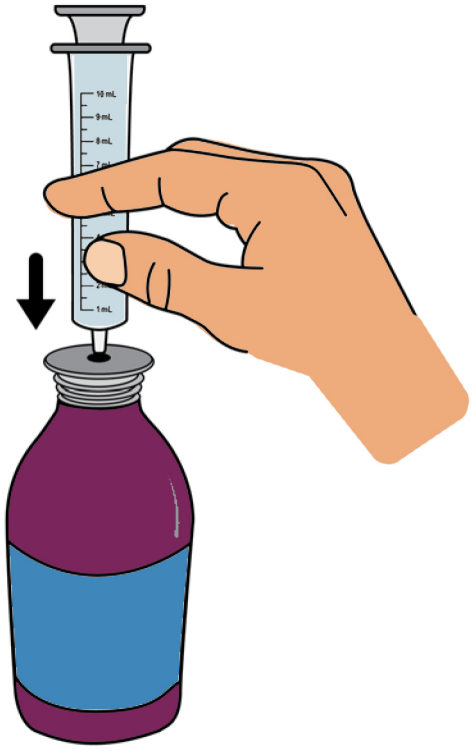


Figure F

Step 7. Turn the bottle upside down. Slowly pull the plunger down to withdraw a small amount of the suspension. Then push the plunger all the way in to remove any air bubbles (see Figure G).

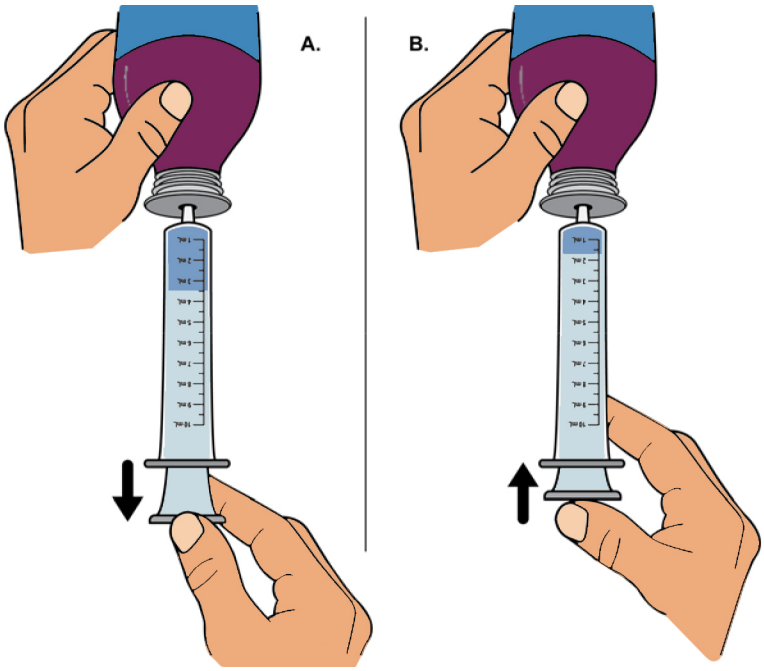


Figure G

Step 8. Slowly pull the plunger down to the 10 mL marking on the oral syringe (see Figure H).

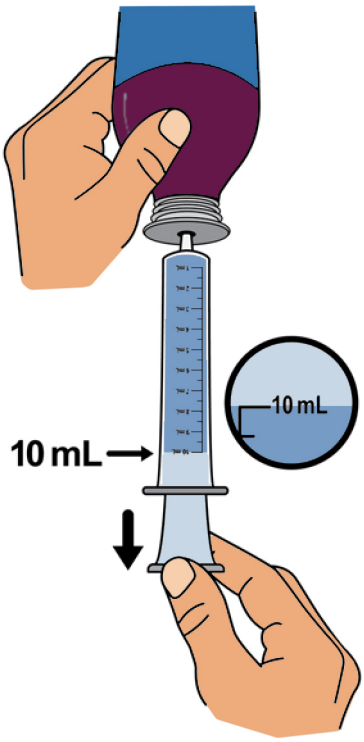


Figure H

Step 9. While keeping the plunger in the same position, turn the bottle upright, and place it carefully on a flat surface. Remove the oral syringe by **gently** twisting or pulling it out from the bottle adapter (see Figure I).

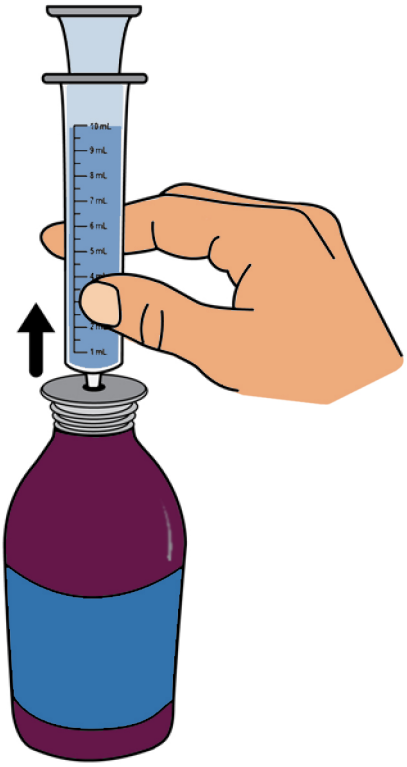


Figure I

Step 10. Check that 10 mL of TIGLUTIK has been drawn up into the oral syringe (see Figure J). If the dose is not correct, insert the oral syringe tip firmly into the bottle adapter. Push the plunger all the way in so that the TIGLUTIK solution flows back into the bottle. Turn the bottle upside down. Repeat Steps 8 and 9.

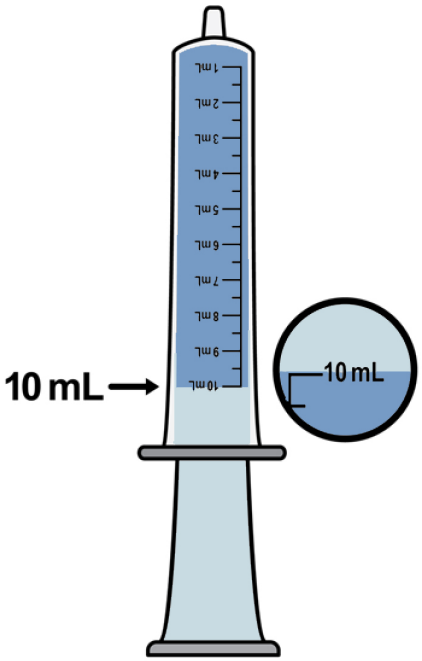


Figure J

PLEASE GO TO NEXT PAGE

You must complete Steps 1 through 10 under "How to Use TIGLUTIK" before starting Step 1 under "How to take a dose of TIGLUTIK oral suspension through a Percutaneous Endoscopic Gastrostomy (PEG) tube."

How to take a dose of TIGLUTIK oral suspension through a Percutaneous Endoscopic Gastrostomy (PEG) tube:

Step 1. Using a catheter-tip syringe, flush the PEG-tube with 1 ounce (30 mL) of water (see Figure N).

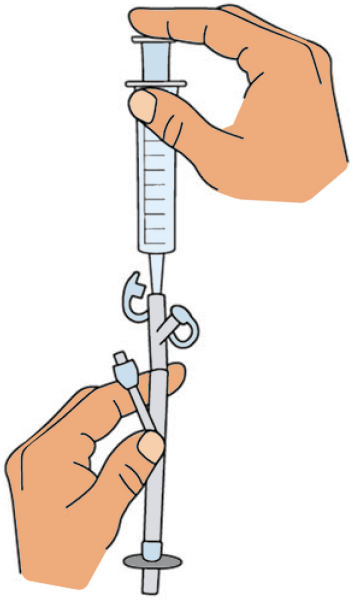


Figure N

Step 2. Place the oral syringe provided (containing the 10 mL of TIGLUTIK) into the PEG tube right away. Slowly push down the plunger until the oral syringe is empty (see Figure O).

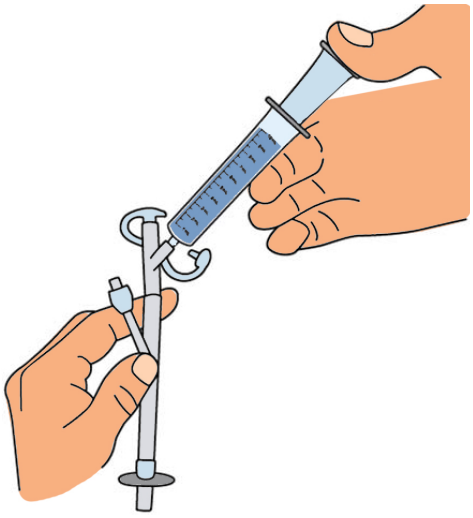


Figure O

Step 3. Using a catheter-tip syringe, flush the PEG tube a second time with 1 ounce (30 mL) of water (see Figure P).

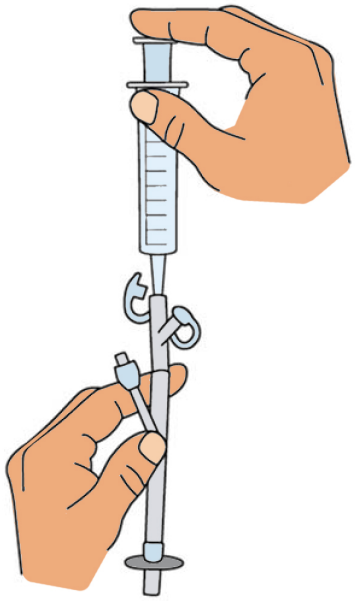


Figure P

Step 4. **Leave the adapter in the bottle.** Place the bottle cap on the bottle and turn the bottle cap clockwise (to the right) to close the bottle (see Figure Q).

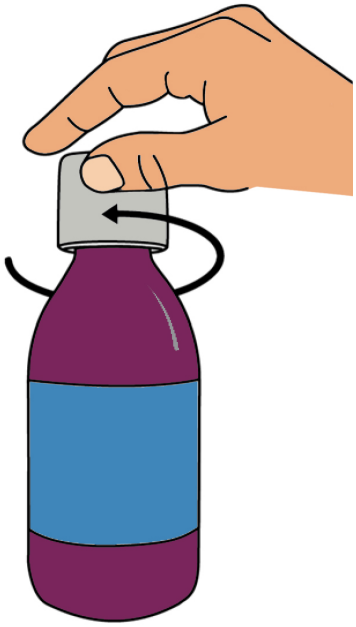


Figure Q

Step 5. Remove the plunger from the oral syringe barrel. Rinse the oral syringe barrel, plunger, and syringe tip cap with water.

When the oral syringe barrel, plunger, and syringe tip cap are dry, put the plunger back into the oral syringe barrel and put the syringe tip cap on the syringe tip. **Do not throw away the oral syringe.** Keep this oral syringe for use with this bottle of TIGLUTIK (see Figure R).

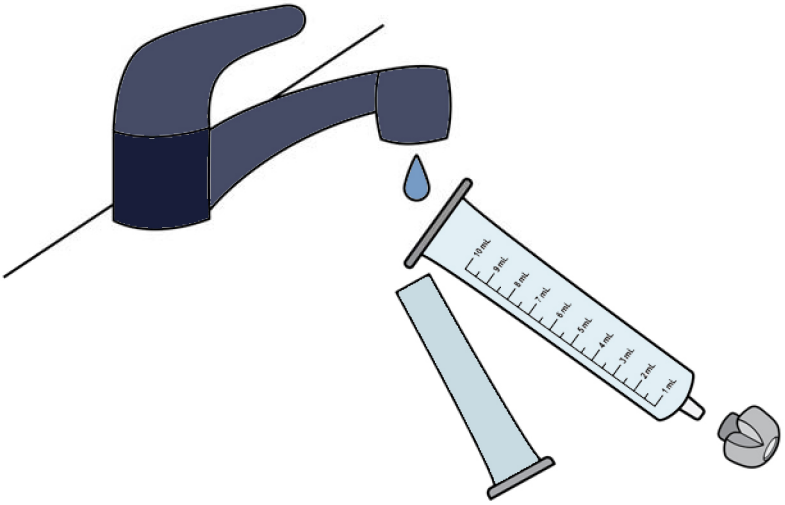


Figure R

Step 6. Store the oral syringe in a clean, dry place.

How to store TIGLUTIK:

- Store TIGLUTIK at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze TIGLUTIK.
- Store TIGLUTIK upright and protect from bright light.
- After opening the bottle of TIGLUTIK, use within 15 days. **Throw away (dispose of) any TIGLUTIK that is not used within 15 days after opening the bottle.** Write the date you open the bottle on the bottle label. Ask your pharmacist how to properly throw away (dispose of) medicines you no longer use.
- Do not use TIGLUTIK after the expiration date (EXP) on the carton and the bottle. The expiration date is the last day of the expiration month.
- Open a new bottle of TIGLUTIK when you are ready to give the first dose.
- Keep bottle tightly closed between each use.
- **Keep TIGLUTIK and all medicines out of the sight and reach of children.**

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

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.

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.

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