

RILUZOLE- riluzole tablet, film coated
Apotex Corp

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use RILUZOLE TABLETS safely and effectively. See full prescribing information for RILUZOLE TABLETS.

RILUZOLE tablets, for oral use

Initial U.S. Approval: 1995

----- **INDICATIONS AND USAGE** -----

Riluzole tablets are indicated for the treatment of amyotrophic lateral sclerosis (ALS) (1)

----- **DOSAGE AND ADMINISTRATION** -----

- Recommended dosage: 50 mg twice daily, taken at least 1 hour before or 2 hours after a meal (2)
- Measure serum aminotransferases before and during treatment (2, 5.1)

----- **DOSAGE FORMS AND STRENGTHS** -----

Tablets: 50 mg (3)

----- **CONTRAINDICATIONS** -----

Patients with a history of severe hypersensitivity reactions to riluzole or to any of its components (4)

----- **WARNINGS AND PRECAUTIONS** -----

- Hepatic injury: Use of riluzole tablets are not recommended in patients with baseline elevations of serum aminotransferases greater than 5 times upper limit of normal; discontinue riluzole tablets if there is evidence of liver dysfunction (5.1)
- Neutropenia: Advise patients to report any febrile illness (5.2)
- Interstitial lung disease: Discontinue riluzole tablets if interstitial lung disease develops (5.3)

----- **ADVERSE REACTIONS** -----

Most common adverse reactions (incidence greater than or equal to 5% and greater than placebo) were asthenia, nausea, dizziness, decreased lung function, and abdominal pain (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Apotex Corp. at 1-800-706-5575 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----- **DRUG INTERACTIONS** -----

- Strong to moderate CYP1A2 inhibitors: Coadministration may increase riluzole tablets-associated adverse reactions (7.1)
- Strong to moderate CYP1A2 inducers: Coadministration may result in decreased efficacy (7.2)
- Hepatotoxic drugs: Riluzole tablets-treated patients that take other hepatotoxic drugs may be at increased risk for hepatotoxicity (7.3)

----- **USE IN SPECIFIC POPULATIONS** -----

- Pregnancy: Based on animal data, may cause fetal harm (8.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 5/2016

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Riluzole tablets are indicated for the treatment of amyotrophic lateral sclerosis (ALS).

2 DOSAGE AND ADMINISTRATION

The recommended dosage for riluzole tablets is 50 mg taken orally twice daily. Riluzole tablets should be taken at least 1 hour before or 2 hours after a meal [see *Clinical Pharmacology (12.3)*].

Measure serum aminotransferases before and during treatment with riluzole tablets [see *Warnings and Precautions (5.1)*].

3 DOSAGE FORMS AND STRENGTHS

50 mg tablets: white to off-white coloured, film-coated, capsule shaped, biconvex and debossed with "APO" on one side and "RI-50" on the other side.

4 CONTRAINDICATIONS

Riluzole tablets are contraindicated in patients with a history of severe hypersensitivity reactions to riluzole or to any of its components (anaphylaxis has occurred) [see *Adverse Reactions (6.1)*].

5 WARNINGS AND PRECAUTIONS

5.1 Hepatic Injury

Cases of drug-induced liver injury, some of which were fatal, have been reported in patients taking riluzole tablets. Asymptomatic elevations of hepatic transaminases have also been reported, and in some patients have recurred upon rechallenge with riluzole tablets.

In clinical studies, the incidence of elevations in hepatic transaminases was greater in riluzole tablets-treated patients than placebo-treated patients. The incidence of elevations of ALT above 5 times the upper limit of normal (ULN) was 2% in riluzole tablets-treated patients. Maximum increases in ALT occurred within 3 months after starting riluzole tablets. About 50% and 8% of riluzole tablets-treated patients in pooled Studies 1 and 2, had at least one elevated ALT level above ULN and above 3 times ULN, respectively [see *Clinical Studies (14)*].

Monitor patients for signs and symptoms of hepatic injury, every month for the first 3 months of treatment, and periodically thereafter. The use of riluzole tablets is not recommended if patients develop hepatic transaminases levels greater than 5 times the ULN. Discontinue riluzole tablets if there is evidence of liver dysfunction (e.g., elevated bilirubin).

5.2 Neutropenia

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

5.3 Interstitial Lung Disease

Interstitial lung disease, including hypersensitivity pneumonitis, has occurred in patients taking riluzole tablets. Discontinue riluzole tablets immediately if interstitial lung disease develops.

6 ADVERSE REACTIONS

The following adverse reactions are described below and elsewhere in the labeling:

- Hepatic Injury [see *Warnings and Precautions (5.1)*]
- Neutropenia [see *Warnings and Precautions (5.2)*]
- Interstitial lung disease [see *Warnings and Precautions (5.3)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse Reactions in Controlled Clinical Trials

In the placebo-controlled clinical trials in patients with ALS (Study 1 and 2), a total of 313 patients received riluzole tablets 50 mg twice daily [see *Clinical Studies (14)*]. The most common adverse reactions in the riluzole tablets group (in at least 5% of patients and more frequently than in the placebo group) were asthenia, nausea, dizziness, decreased lung function, and abdominal pain. The most common adverse reactions leading to discontinuation in the riluzole tablets group were nausea, abdominal pain, constipation, and elevated ALT.

There was no difference in rates of adverse reactions leading to discontinuation in females and males. However, the incidence of dizziness was higher in females (11%) than in males (4%). The adverse reaction profile was similar in older and younger patients. There were insufficient data to determine if

there were differences in the adverse reaction profile in different races.

Table 1 lists adverse reactions that occurred in at least 2% of riluzole tablets-treated patients (50 mg twice daily) in pooled Study 1 and 2, and at a higher rate than placebo.

Table 1. Adverse Reactions in Pooled Placebo-Controlled Trials (Studies 1 and 2) in Patients with ALS

	Riluzole tablets 50 mg twice daily (N=313)	Placebo (N=320)
Asthenia	19%	12%
Nausea	16%	11%
Decreased lung function	10%	9%
Hypertension	5%	4%
Abdominal pain	5%	4%
Vomiting	4%	2%
Arthralgia	4%	3%
Dizziness	4%	3%
Dry mouth	4%	3%
Insomnia	4%	3%
Pruritus	4%	3%
Tachycardia	3%	1%
Flatulence	3%	2%
Increased cough	3%	2%
Peripheral edema	3%	2%
Urinary Tract Infection	3%	2%
Circumoral paresthesia	2%	0%
Somnolence	2%	1%
Vertigo	2%	1%
Eczema	2%	1%

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of riluzole tablets. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Acute hepatitis and icteric toxic hepatitis [see Warnings and Precautions (5.1)]
- Renal tubular impairment

7 DRUG INTERACTIONS

7.1 Agents that may Increase Riluzole Blood Concentrations

CYP1A2 inhibitors

Co-administration of riluzole tablets (a CYP1A substrate) with CYP1A2 inhibitors was not evaluated in a clinical trial; however, *in vitro* findings suggest an increase in riluzole exposure is likely. The

concomitant use of strong or moderate CYP1A2 inhibitors (e.g., ciprofloxacin, enoxacin, fluvoxamine, methoxsalen, mexiletine, oral contraceptives, thiabendazole, vemurafenib, zileuton) with riluzole tablets may increase the risk of riluzole tablets-associated adverse reactions [see *Clinical Pharmacology (12.3)*].

7.2 Agents that may Decrease Riluzole Plasma Concentrations

CYP1A2 inducers

Co-administration of riluzole tablets (a CYP1A substrate) with CYP1A2 inducers was not evaluated in a clinical trial; however, *in vitro* findings suggest a decrease in riluzole exposure is likely. Lower exposures may result in decreased efficacy [see *Clinical Pharmacology (12.3)*].

7.3 Hepatotoxic drugs

Clinical trials in ALS patients excluded patients on concomitant medications which were potentially hepatotoxic, (e.g., allopurinol, methyldopa, sulfasalazine). Riluzole tablets-treated patients who take other hepatotoxic drugs may be at an increased risk for hepatotoxicity [see *Warnings and Precautions (5.1)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no studies of riluzole tablets in pregnant women, and case reports have been inadequate to inform the drug-associated risk. The background risk for major birth defects and miscarriage in patients with amyotrophic lateral sclerosis is unknown. In the U.S. general population, the background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

In studies in which riluzole was administered orally to pregnant animals, developmental toxicity (decreased embryofetal/offspring viability, growth, and functional development) was observed at clinically relevant doses [see *Data*]. Based on these results, women should be advised of a possible risk to the fetus associated with use of riluzole tablets during pregnancy.

Data

Animal Data

Oral administration of riluzole (3, 9, or 27 mg/kg/day) to pregnant rats during the period of organogenesis resulted in decreases in fetal growth (body weight and length) at the high dose. The mid dose, a no-effect dose for embryofetal developmental toxicity, is approximately equal to the recommended human daily dose (RHDD, 100 mg) on a mg/m² basis. When riluzole was administered orally (3, 10, or 60 mg/kg/day) to pregnant rabbits during the period of organogenesis, embryofetal mortality was increased at the high dose and fetal body weight was decreased and morphological variations increased at all but the lowest dose tested. The no-effect dose (3 mg/kg/day) for embryofetal developmental toxicity is less than the RHDD on a mg/m² basis. Maternal toxicity was observed at the highest dose tested in rat and rabbit.

When riluzole was orally administered (3, 8, or 15 mg/kg/day) to male and female rats prior to and during mating and to female rats throughout gestation and lactation, increased embryofetal mortality and decreased postnatal offspring viability, growth, and functional development were observed at the high dose. The mid dose, a no-effect dose for pre- and postnatal developmental toxicity, is approximately equal to the RHDD on a mg/m² basis.

8.2 Lactation

Risk Summary

It is not known if riluzole is excreted in human milk. Riluzole or its metabolites have been detected in

milk of lactating rat. Women should be advised that many drugs are excreted in human milk and that the potential for serious adverse reactions in nursing infants from riluzole tablets is unknown.

8.3 Females and Males of Reproductive Potential

In rats, oral administration of riluzole resulted in decreased fertility indices and increases in embryolethality [see *Nonclinical Toxicology (13.1)*].

8.4 Pediatric Use

Safety and effectiveness of riluzole tablets in pediatric patients have not been established.

8.5 Geriatric Use

In clinical studies of riluzole tablets, 30% of patients were 65 years and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

8.6 Hepatic Impairment

Patients with mild [Child-Pugh's (CP) score A] or moderate (CP score B) hepatic impairment 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. The impact of severe hepatic impairment on riluzole exposure is unknown.

Use of riluzole tablets is not recommended in patients with baseline elevation or elevations of serum aminotransferases greater than 5 times upper limit of normal or evidence of liver dysfunction (e.g., elevated bilirubin) [see *Clinical Pharmacology (12.3)*].

8.7 Japanese Patients

Japanese patients are more likely to have higher riluzole concentrations. Consequently, the risk of adverse reactions may be greater in Japanese patients [see *Clinical Pharmacology (12.3)*].

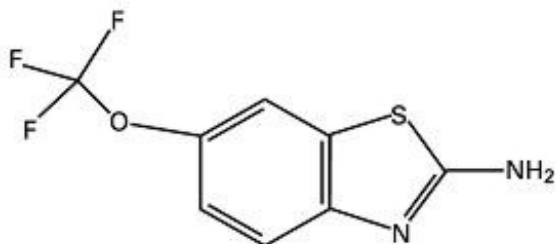
10 OVERDOSAGE

Reported symptoms of overdose following ingestion of riluzole tablets ranging from 1.5 to 3 grams (30 to 60 times the recommended dose) included acute toxic encephalopathy, coma, drowsiness, memory loss, and methemoglobinemia.

No specific antidote for the treatment of riluzole tablets overdose is available. For current information on the management of poisoning or overdose, contact the National Poison Control Center at 1-800-222-1222 or www.poisson.org.

11 DESCRIPTION

Riluzole is a member of the benzothiazole class. Chemically, riluzole is 2-amino-6-(trifluoromethoxy)benzothiazole. Its molecular formula is $C_8H_5F_3N_2OS$, and its molecular weight is 234.2. Its structural formula is as follows:



Riluzole USP is a white to slightly yellow powder that is very soluble in dimethylformamide, dimethylsulfoxide and methanol; freely soluble in dichloromethane; sparingly soluble in 0.1 N HCl; and very slightly soluble in water and in 0.1 N NaOH. Riluzole tablets, USP is available as a capsule-shaped, white to off-white, film-coated, biconvex tablet for oral administration containing 50 mg of riluzole. Each tablet is debossed with "APO" on one side and "RI-50" on the other side.

Inactive Ingredients

Core: dibasic calcium phosphate dihydrate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose.

Film coating: hypromellose, polyethylene glycol, talc, titanium dioxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism by which riluzole exerts its therapeutic effects in patients with ALS is unknown.

12.2 Pharmacodynamics

The clinical pharmacodynamics of riluzole has not been determined in humans.

12.3 Pharmacokinetics

Table 2 displays the pharmacokinetic parameters of riluzole.

Table 2. Pharmacokinetic Parameters of Riluzole

Absorption	
Bioavailability (oral)	Approximately 60%
Dose Proportionality	Linear over a dose range of 25 mg to 100 mg every 12 hours (1/2 to 2 times the recommended dosage)
Food effect	AUC ↓ 20% and C _{max} ↓ 45% (high fat meal)
Distribution	
Plasma Protein Binding	96% (Mainly to albumin and lipoproteins)
Elimination	
Elimination half-life	<ul style="list-style-type: none"> • 12 hours (CV=35%) • The high interindividual variability in the clearance of riluzole is potentially attributable to variability of CYP1A2. The clinical implications are not known.
Accumulation	Approximately 2-fold
Metabolism	
Fraction metabolized (% dose)	At least 88%
Primary metabolic pathway(s) [<i>in vitro</i>]	<ul style="list-style-type: none"> • Oxidation: CYP1A2 • Direct and sequential glucuronidation: UGT-HP4
Active	Some metabolites appear pharmacologically active <i>in vitro</i> , but the

Metabolites	clinical implications are not known.
<i>Excretion</i>	
Primary elimination pathways (% dose)	<ul style="list-style-type: none"> • Feces: 5% • Urine: 90% (2% unchanged riluzole)

Specific Populations

Hepatic Impairment

Compared with healthy volunteers, the AUC of riluzole was approximately 1.7-fold greater in patients with mild chronic hepatic impairment (CP score A) and approximately 3-fold greater in patients with moderate chronic hepatic impairment (CP score B). The pharmacokinetics of riluzole have not been studied in patients with severe hepatic impairment (CP score C) [see *Use in Specific Populations (8.6)*].

Race

The clearance of riluzole was 50% lower in male Japanese subjects than in Caucasian subjects, after normalizing for body weight [see *Use in Specific Populations (8.7)*].

Gender

The mean AUC of riluzole was approximately 45% higher in female patients than male patients.

Smokers

The clearance of riluzole in tobacco smokers was 20% greater than in nonsmokers.

Geriatric Patients and Patients with Moderate to Severe Renal Impairment

Age 65 years or older, and moderate to severe renal impairment do not have a meaningful effect on the pharmacokinetics of riluzole. The pharmacokinetics of riluzole in patients undergoing hemodialysis are unknown.

Drug Interaction Studies

Drugs Highly Bound To Plasma Proteins

Riluzole and warfarin are highly bound to plasma proteins. *In vitro*, riluzole did not show any displacement of warfarin from plasma proteins. Riluzole binding to plasma proteins was unaffected by warfarin, digoxin, imipramine and quinine at high therapeutic concentrations *in vitro*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Riluzole was not carcinogenic in mice or rats when administered for 2 years at daily oral doses up to 20 and 10 mg/kg/day, respectively, which are approximately equal to the recommended human daily dose (RHDD, 100 mg) on a mg/m² basis.

Mutagenesis

Riluzole was negative in *in vitro* (bacterial reverse mutation (Ames), mouse lymphoma *tk*, chromosomal aberration assay in human lymphocytes), and *in vivo* (rat cytogenetic and mouse micronucleus) assays.

N-hydroxyriluzole, the major active metabolite of riluzole, was positive for clastogenicity in the *in vitro* mouse lymphoma *tk* assay and in the *in vitro* micronucleus assay using the same mouse lymphoma cell line. N-hydroxyriluzole was negative in the HPRT gene mutation assay, the Ames assay (with and without rat or hamster S9), the *in vitro* chromosomal aberration assay in human lymphocytes, and the *in vivo* mouse micronucleus assay.

Impairment of Fertility

When riluzole (3, 8, or 15 mg/kg) was administered orally to male and female rats prior to and during

mating and continuing in females throughout gestation and lactation, fertility indices were decreased and embryolethality was increased at the high dose. This dose was also associated with maternal toxicity. The mid dose, a no-effect dose for effects on fertility and early embryonic development, is approximately equal to the RHDD on a mg/m² basis.

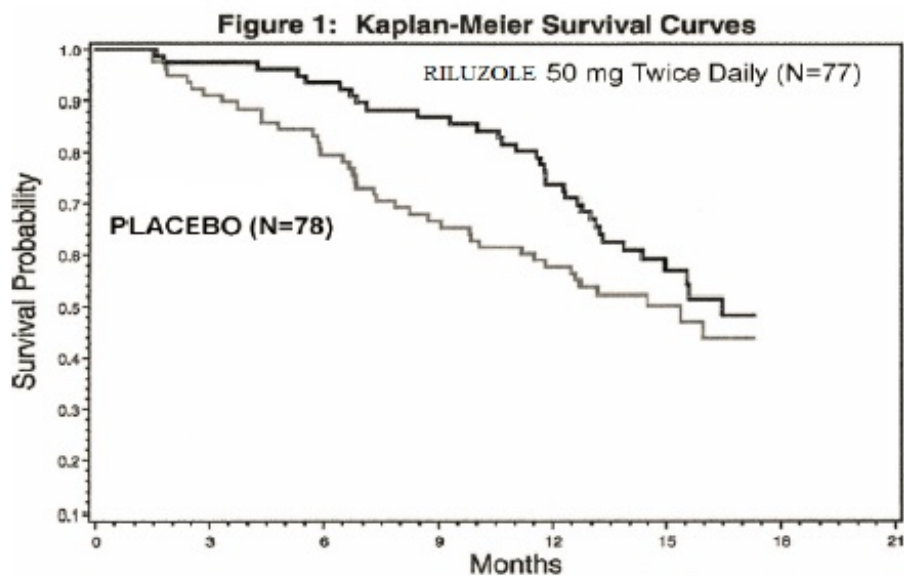
14 CLINICAL STUDIES

The efficacy of riluzole tablets was demonstrated in two studies (Study 1 and 2) that evaluated riluzole tablets 50 mg twice daily in patients with amyotrophic lateral sclerosis (ALS). Both studies included patients with either familial or sporadic ALS, a disease duration of less than 5 years, and a baseline forced vital capacity greater than or equal to 60% of normal.

Study 1 was a randomized, double-blind, placebo-controlled clinical study that enrolled 155 patients with ALS. Patients were randomized to receive riluzole tablets 50 mg twice daily (n=77) or placebo (n=78) and were followed for at least 13 months (up to a maximum duration of 18 months). The clinical outcome measure was time to tracheostomy or death.

The time to tracheostomy or death was longer for patients receiving riluzole tablets compared to placebo. There was an early increase in survival in patients receiving riluzole tablets compared to placebo. Figure 1 displays the survival curves for time to death or tracheostomy. The vertical axis represents the proportion of individuals alive without tracheostomy at various times following treatment initiation (horizontal axis). Although these survival curves were not statistically significantly different when evaluated by the analysis specified in the study protocol (Logrank test p=0.12), the difference was found to be significant by another appropriate analysis (Wilcoxon test p=0.05). As seen in Figure 1, the study showed an early increase in survival in patients given riluzole tablets. Among the patients in whom the endpoint of tracheostomy or death was reached during the study, the difference in median survival between the riluzole tablets 50 mg twice daily and placebo groups was approximately 90 days.

Figure 1. Time to Tracheostomy or Death in ALS Patients in Study 1 (Kaplan-Meier Curves)



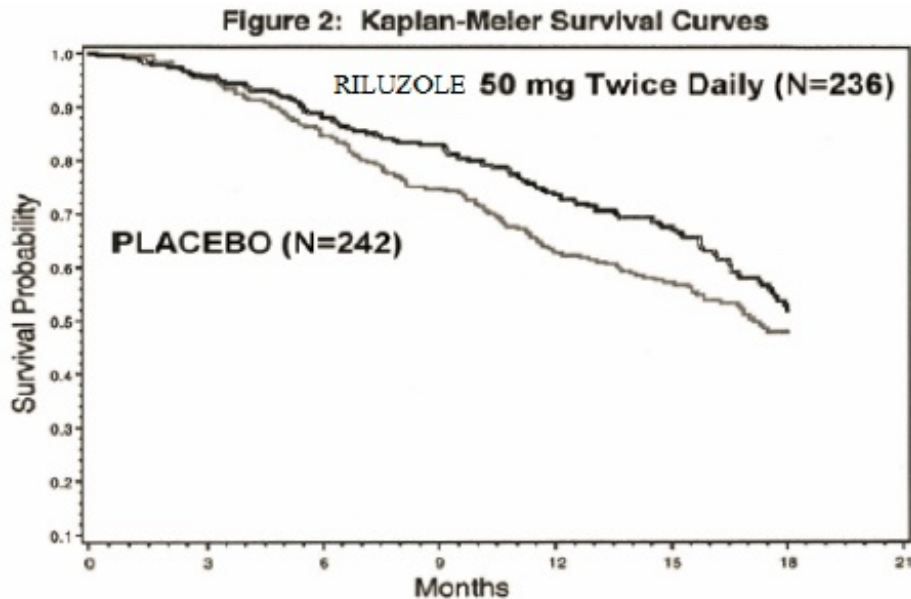
Study 2 was a randomized, double-blind, placebo-controlled clinical study that enrolled 959 patients with ALS. Patients were randomized to riluzole tablets 50 mg twice daily (n=236) or placebo (n=242) and were followed for at least 12 months (up to a maximum duration of 18 months). The clinical outcome measure was time to tracheostomy or death.

The time to tracheostomy or death was longer for patients receiving riluzole tablets compared to placebo. Figure 2 displays the survival curves for time to death or tracheostomy for patients randomized to either riluzole tablets 100 mg per day or placebo. Although these survival curves were

not statistically significantly different when evaluated by the analysis specified in the study protocol (Logrank test $p=0.076$), the difference was found to be significant by another appropriate analysis (Wilcoxon test $p=0.05$). Not displayed in Figure 2 are the results of riluzole tablets 50 mg per day (one-half of the recommended daily dose), which could not be statistically distinguished from placebo, or the results of riluzole tablets 200 mg per day (two times the recommended daily dose), which were not distinguishable from the 100 mg per day results. Among the patients in whom the endpoint of tracheostomy or death was reached during the study, the difference in median survival between riluzole tablets and placebo was approximately 60 days.

Although riluzole tablets improved survival in both studies, measures of muscle strength and neurological function did not show a benefit.

Figure 2. Time to Tracheostomy or Death in ALS Patients in Study 2 (Kaplan-Meier Curves)



16 HOW SUPPLIED/STORAGE AND HANDLING

Riluzole tablets, USP are white to off-white coloured, film-coated, capsule shaped, biconvex and debossed with "APO" on one side and "RI-50" on the other side. Riluzole tablets, USP are supplied in bottles of 60 tablets, NDC 60505-3285-6.

STORE AT 20° TO 25°C (68° TO 77°F); EXCURSIONS PERMITTED FROM 15° TO 30°C (59° TO 86°F) [See USP Controlled Room Temperature]. DISPENSE IN A TIGHT, LIGHT RESISTANT CONTAINER [SEE USP].

KEEP OUT OF THE REACH OF CHILDREN.

17 PATIENT COUNSELING INFORMATION

Advise patients to inform their healthcare provider if they experience:

- Yellowing of the whites of the eyes [see Warnings and Precautions (5.1)]
- Fever [see Warnings and Precautions (5.2)]
- Respiratory symptoms—for example, dry cough and difficult or labored breathing [see Warnings and Precautions (5.3)]

**APOTEX INC.
RILUZOLE TABLETS, USP
50 mg**

Manufactured by Apotex Research Pvt. Ltd
Manufactured for Apotex Corp.
 Bangalore – 560 099
 Weston, Florida 33326
 India

Revised: May 2016
 Rev. 1

PRINCIPAL DISPLAY PANEL – 50 mg Bottle Label

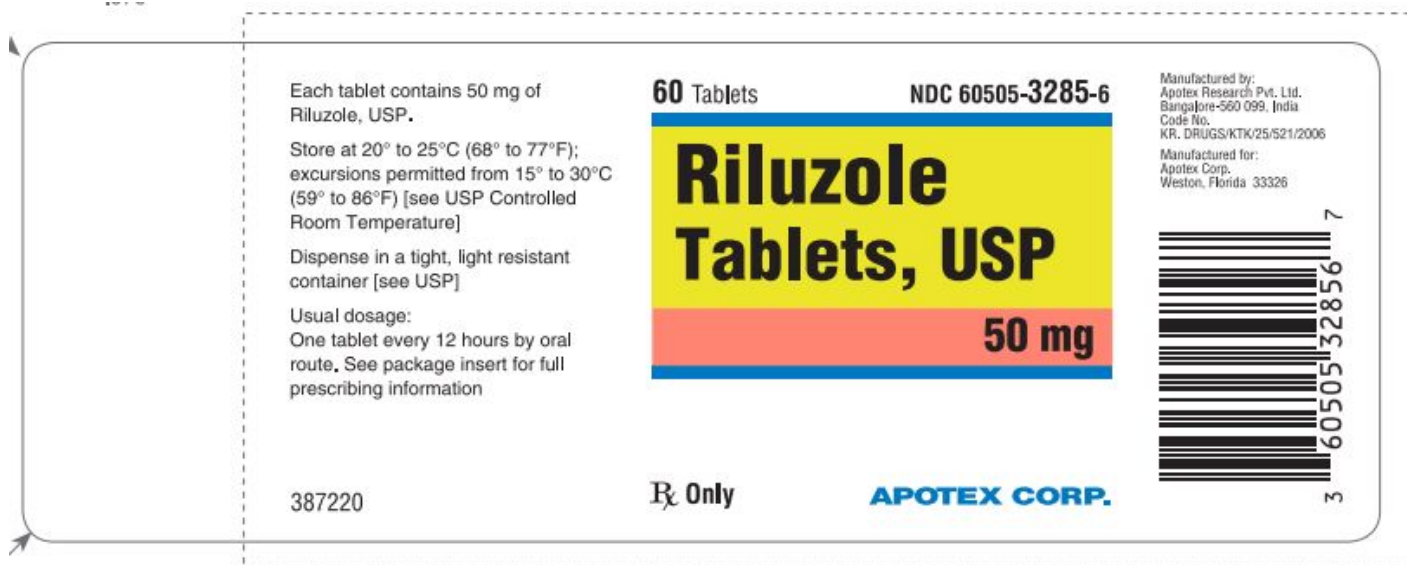
APOTEX CORP. NDC 60505-3285-6

Riluzole Tablets, USP

50 mg

Rx Only

60 tablets



RILUZOLE			
riluzole tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60505-3285
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	RILUZOLE (UNII: 7LJ087RS6F) (RILUZOLE - UNII:7LJ087RS6F)	RILUZOLE	50 mg

Inactive Ingredients

Ingredient Name	Strength
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (white to off white)	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	APO;RI;50
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60505-3285-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091300	06/18/2013	

Labeler - Apotex Corp (845263701)

Registrant - Apotex Inc. (209429182)

Establishment

Name	Address	ID/FEI	Business Operations
Apotex Research Private Limited		862584104	manufacture(60505-3285) , analysis(60505-3285)