



| National shared care protocol for riluzole for motor neurone disease within adult services |           |
|--|-----------|
| Adapted and adopted for use in NHS Frimley   |           |
| Agreed by NHS Frimley Medicines Optimisation Group   | July 2024 |
| Agreed by FHFT DTC   | June 2024 |
| Ratified by NHS Frimley Medicines Board  | July 2024 |
| Review date  | July 2029 |

## Riluzole for motor neurone disease within adult services

The content of this shared care protocol was correct as of the date of approval. As well as these protocols, please ensure that [summaries of product characteristics](#) (SPCs), [British national formulary](#) (BNF) or the [Medicines and Healthcare products Regulatory Agency](#) (MHRA) or [NICE](#) websites are reviewed for up-to-date information on any medicine.

### Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol ([section 2](#)) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see [section 11](#)) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions (see [section 4](#)) and interactions (see [section 7](#)).
- Conduct required baseline investigations and initial monitoring (see [section 8](#)).
- Initiate and optimise treatment as outlined in [section 5](#). Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information ([section 13](#)).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.



- Conduct the required monitoring in [section 8](#) and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#) remains appropriate.
- Provide advice to primary care on the management of adverse effects if required.

### Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- Check local formulary status and, if accepted, prescribe ongoing treatment as detailed in the specialist's request and as per [section 5](#), taking into account potential drug interactions in [section 7](#).
- Adjust the dose prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in [section 9](#). Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in [section 10](#) and discuss with specialist team when required.
- Stop medication and make an urgent referral to the specialist if bone marrow suppression is suspected.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

### Patient and/or carer responsibilities

- Take medication as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in [section 11](#).
- Report the use of any over the counter medications to their prescriber and be aware they should discuss the use of specialist medication with their pharmacist before purchasing any OTC medicines.
- Not to drive or operate heavy machinery if medication affects their ability to do so safely.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant

## 1. Background

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Excessive stimulation of glutamate receptors may cause or play an important role in the destruction of motor neurone disease. In vitro riluzole inhibits the release of glutamate, thereby decreasing the firing of motor neurones induced by glutamate receptor agonists thus protecting cells from glutamate-mediated damage.

A Cochrane review (2012) concluded that riluzole 100mg daily is reasonably safe and probably prolongs median survival by approximately 2-3 months.

NICETA20 recommends riluzole for the treatment of individuals with the amyotrophic lateral sclerosis (ALS) form of motor neurone disease (MND). It goes on to recommend that:

“Riluzole therapy should be initiated by a neurological specialist with expertise in the management of MND. Routine supervision of therapy should be managed by locally agreed shared care protocols undertaken by general practitioners.”

This information sheet does not replace the SmPC, which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.

## 2. Indications

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The licensed indications covered by the document are:

- Amyotrophic lateral sclerosis (ALS) form of motor neurone disease (MND)

This shared care protocol applies to people from the age of 18 year old.

The Frimley formulary status is Amber with Shared Care and so prescribing can move to primary care in line with this document.

## 3. Locally agreed off-label use

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Nil

## 4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see [BNF](#) & [SPC](#) for comprehensive information.

### Contraindications:

- Severe hypersensitivity to riluzole or any of the excipients
- Hepatic disease or baseline transaminases greater than 3 times the upper limit of normal

- Patients who are pregnant or lactating
- Acute porphyrias

**Cautions:**

- History of abnormal hepatic function
- Interstitial lung disease

## 5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after 4 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

**Initial stabilisation (1 month):**

50mg twice daily orally

If patients are unable to swallow tablets, the tablets may be crushed for administration via a PEG or nasogastric tube or mixed with a soft food product.

**The loading period must be prescribed by the initiating specialist.**

**Maintenance dose (following initial stabilisation):**

50mg twice daily orally

## 6. Pharmaceutical aspects

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|                          |         |
|--------------------------|---------|
| Route of administration: | Oral    |
| Formulation:             | Tablets |

|                              |   |
|------------------------------|---|
| Administration details:      | If patients are unable to swallow tablets, the tablets may be crushed for administration via a PEG or nasogastric tube or mixed with a soft food product. |
| Other important information: | Nil   |

## 7. Significant medicine interactions

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The following list is not exhaustive. Please see [BNF](#) or [SPC](#) for comprehensive information and recommended management.

Riluzole is metabolised by CYP1A2 hence potential for CYP1A2 interactions. The clinical significance has not been established.

- Inhibitors of CYP1A2 – cimetidine, macrolide and quinolone antibiotics
- Inducers of CYP1A2 – rifampicin
- Drugs metabolised by CYP1A2 – warfarin, verapamil, theophylline, tricyclic antidepressants

Combined hormonal contraceptives are predicted to increase the exposure to Riluzole. Manufacturer makes no recommendation.

## 8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

### Baseline investigations:

- Monitor hepatic transaminases, including ALT, at baseline

### Initial monitoring (including frequency):

- Monitor hepatic transaminases, including ALT, at baseline and every month for the first 3 months of treatment

### Ongoing monitoring (including frequency):

The specialist will retain the responsibility for monitoring the patient's ongoing response to treatment, and advise if a dose change or treatment cessation is appropriate. This will be undertaken at least annually.

After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.

## 9. Ongoing monitoring requirements to be undertaken by primary care

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See [section 10](#) for further guidance on management of adverse effects/responding to monitoring results. Funding for monitoring in primary care has been agreed from 1<sup>st</sup> July 2024 onwards.

| Monitoring and advice  | Frequency   |
|--|---|
| <p>Monitor hepatic transaminases, including ALT</p> <p><b>Stop if ALT is greater than five times upper limit of normal</b></p>   | <p><b>The exact frequency of monitoring to be communicated by the specialist in all cases.</b></p> <p>Every 3 months until the individual has been taking the medication for 12 months. Then 6 monthly thereafter</p> |
| <p>For those with renal impairment: check renal function every 6 months</p> <ul style="list-style-type: none"> <li>Manufacturers do not have data and therefore cannot recommend use in renally impaired patients: risks/benefit to be considered</li> </ul> | <p>Every 6 months</p>   |
| <p>Check white blood cell counts in febrile illness and to stop riluzole if patient is found to be neutropenic</p> <p><b>Stop if neutropenic (&lt;1x10<sup>-9</sup>/L)</b></p>   | <p>If febrile</p>   |
| <p><b>If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.</b></p>   |   |

## 10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

For information on incidence of ADRs see relevant summaries of product characteristics

| Result   | Action for primary care  |
|--|--|
| <b>As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance</b> |  |
| ALT is greater than five times upper limit of normal   | Stop riluzole and contact specialist team for urgent advice  |
| Neutropenic ( $<1 \times 10^{-9}/L$ )  | Stop riluzole and contact specialist team for urgent advice<br><br><b>Patients or their carers should be told how to recognise signs of neutropenia and advised to seek immediate medical attention if symptoms such as fever occur.</b> |
| Abdominal pain; asthenia; diarrhoea; dizziness; drowsiness; headache; nausea; oral disorders; pain; tachycardia; vomiting  | Ensure patient knows that these adverse effects can occur commonly.<br><br><b>Dizziness or vertigo may affect performance of skilled tasks (e.g. driving).</b>   |

## 11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

**The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:**

- Patients or their carers should be told how to recognise signs of neutropenia and advised to seek immediate medical attention if symptoms such as fever occur.

**The patient should be advised:**

- Dizziness or vertigo may affect performance of skilled tasks (e.g. driving).

**Patient information resources:**

## 12. **Pregnancy, paternal exposure and breast feeding**

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

### **Pregnancy:**

Avoid—no information available.

### **Breastfeeding:**

Avoid—no information available.

### **Paternal exposure:**

No information available.

### 13. Specialist contact information

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Name: *Dr Jeremy Stern, Gina Monk*

Daytime telephone number: 0300 613 2512 or 07824147436

Email address: [fhft.neuromedsecs@nhs.net](mailto:fhft.neuromedsecs@nhs.net) or [g.monk@nhs.net](mailto:g.monk@nhs.net)

### 14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement should be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

### 15. References

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- <https://bnf.nice.org.uk/drugs/riluzole/>
- <https://www.medicines.org.uk/emc/product/5185/smpc>
- <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001447.pub3/full>

### 16. Other relevant national guidance

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- <https://www.nice.org.uk/guidance/ta20/chapter/1-Recommendations>
- x <https://www.nice.org.uk/guidance/ng42>

### 17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

**Contact details for specialist given in section 13.**

## Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*

Date of birth: *[insert date of birth]*

NHS Number: *[insert NHS Number]*

Diagnosis: *[insert diagnosis]*

As per the agreed *Frimley* shared care protocol for *[insert medicine name]* for the treatment of *[insert indication]*, this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

|   | Specialist to complete |
|---|------------------------|
| <i>The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:</i>                                       |                        |
| <i>Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory</i>                                  | Yes / No               |
| <i>The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care</i>                           | Yes / No               |
| <i>The risks and benefits of treatment have been explained to the patient</i>   | Yes / No               |
| <i>The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed</i>                             | Yes / No               |
| <i>The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments</i> | Yes / No               |
| <i>I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)</i>                   | Yes / No               |
| <i>I have included with the letter copies of the information the patient has received</i>   | Yes / No               |
| <i>I have provided the patient with sufficient medication to last until</i>   |                        |
| <i>I have arranged a follow up with this patient in the following timescale</i>   |                        |

Treatment was started on *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you are in agreement, please undertake monitoring and treatment from *[insert date]*

NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

# Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

## Primary Care Prescriber Response

Dear *[insert Doctor's name]*  
Patient *[insert Patient's name]*  
NHS Number *[insert NHS Number]*  
Identifier *[insert patient's date of birth and/or address]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

| Medicine | Route | Dose & frequency |
|----------|-------|------------------|
|          |       |                  |

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: \_\_\_\_\_ Date:  
\_\_\_\_\_

Primary Care Prescriber address/practice stamp

## Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

**Re:**

Patient *[insert Patient's name]*  
 NHS Number *[insert NHS Number]*  
 Identifier *[insert patient's date of birth and/or address]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *Frimley*, in conjunction with local acute trusts have classified *[insert medicine name]* as a Shared Care drug, and requires a number of conditions to be met before transfer can be made to primary care.

**I regret to inform you that in this instance I am unable to take on responsibility due to the following:**

|    |  | Tick which apply |
|----|--|------------------|
| 1. | <p><b>The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care</b></p> <p>As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because <i>[insert reason]</i>. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice.</p> <p><b>I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.</b></p> |                  |
| 2. | <p><b>The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement</b></p> <p>As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.</p> <p><b>Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you</b></p>   |                  |

|    |   |  |
|----|---|--|
| 3. | <p><b>A minimum duration of supply by the initiating clinician</b></p> <p>As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p><b><i>Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.</i></b></p>   |  |
| 4. | <p><b>Initiation and optimisation by the initiating specialist</b></p> <p>As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p><b><i>Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.</i></b></p>   |  |
| 5. | <p><b>Shared Care Protocol not received</b></p> <p>As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed.</p> <p>For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p><b><i>Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.</i></b></p> |  |
| 6. | <p><b>Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)</b></p>   |  |

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and

the dissemination of sufficient, up-to-date information to individual GPs.” In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

**Primary Care Prescriber signature:** \_\_\_\_\_  
**Date:** \_\_\_\_\_

**Primary Care Prescriber address/practice stamp**