

# Rufinamide

ESCA: Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years of age and older

## AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of rufinamide for epileptic seizures can be shared between the specialist and general practitioner (GP). You are invited to participate however, if you do not feel competent to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with for epileptic seizures are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

**The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

### RESPONSIBILITIES and ROLES

| Specialist responsibilities |                                                                                                                                                                    |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.                          | Confirm the diagnosis of epileptic seizures in Lennox-Gastaut syndrome                                                                                             |
| 2.                          | Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient                                                            |
| 3.                          | Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made |
| 4.                          | Do baseline monitoring prior to initiation of rufinamide                                                                                                           |
| 5.                          | Initiate treatment and stabilise dose of rufinamide                                                                                                                |
| 6.                          | Review the patient's condition and monitor response to treatment regularly                                                                                         |
| 7.                          | A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay                                      |
| 8.                          | Report serious adverse events to the MHRA                                                                                                                          |
| 9.                          | Ensure clear backup arrangements exist for GPs, for advice and support (Please complete details below)                                                             |

| General Practitioner responsibilities                                                                                                                                               |           |                         |  |                       |           |             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-------------------------|--|-----------------------|-----------|-------------|
| 1. Reply to the request for shared care as soon as practicable i.e. within 10 working days                                                                                          |           |                         |  |                       |           |             |
| 2. Prescribe rufinamide at the dose recommended                                                                                                                                     |           |                         |  |                       |           |             |
| 3. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement                               |           |                         |  |                       |           |             |
| GP Prescribing System                                                                                                                                                               | Read Code | Description             |  | GP Prescribing System | Read Code | Description |
| EMIS and Vision                                                                                                                                                                     | 8BM5.00   | Shared care prescribing |  | SystemOne             | XaB58     | Shared care |
| 4. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist                                                                                       |           |                         |  |                       |           |             |
| 5. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment |           |                         |  |                       |           |             |
| 6. Refer back to specialist if condition deteriorates                                                                                                                               |           |                         |  |                       |           |             |
| 7. Report serious adverse events to specialist and MHRA                                                                                                                             |           |                         |  |                       |           |             |
| 8. Stop treatment on advice of specialist                                                                                                                                           |           |                         |  |                       |           |             |

| Patient's role |                                                                                                                             |
|----------------|-----------------------------------------------------------------------------------------------------------------------------|
| 1.             | Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment |
| 2.             | Share any concerns in relation to treatment with rufinamide with the specialist, clinical nurse specialist or GP            |
| 3.             | Report any adverse effects to the specialist or GP whilst taking rufinamide                                                 |
| 4.             | Attend regular outpatient appointments with the specialist                                                                  |

**Please enter Specialist contact details and patient specific information in Appendix 1**

## SUPPORTING INFORMATION

|                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                      |                           |              |                |                |          |                          |                           |                           |                           |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|---------------------------|--------------|----------------|----------------|----------|--------------------------|---------------------------|---------------------------|---------------------------|
| <b>Indication</b>                               | Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years of age and older                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                      |                           |              |                |                |          |                          |                           |                           |                           |
| <b>Dosage and Administration</b>                | <p><u>Use in children four years of age or older and less than 30 kg</u><br/> <i>Patients &lt;30 kg not receiving valproate:</i><br/>           Treatment should be initiated at a daily dose of 200 mg (5 ml dosing suspension given as two 2.5 ml doses, one in the morning and one in the evening). According to clinical response and tolerability, the dose may be increased by 200 mg/day increments, as frequently as every two days, up to a maximum recommended dose of 1000 mg/day (25 ml/day). Doses of up to 3600 mg/day (90 ml/day) have been studied in a limited number of patients.</p> <p><i>Patients &lt;30 kg also receiving valproate:</i><br/>           As valproate significantly decreases clearance of rufinamide, a lower maximum dose of rufinamide is recommended for patients &lt;30 kg being co-administered valproate. Treatment should be initiated at a daily dose of 200 mg. According to clinical response and tolerability, after a minimum of 2 days the dose may be increased by 200 mg/day, to the maximum recommended dose of 600 mg/day (15 ml/day).</p> <p><u>Use in adults, adolescents and children four years of age or older of 30 kg or over</u><br/>           Treatment should be initiated at a daily dose of 400 mg (10 ml dosing suspension given as two 5 ml doses). According to clinical response and tolerability, the dose may be increased by 400 mg/day increments, as frequently as every two days, up to a maximum recommended dose as indicated in the table below.</p> <table border="1"> <tr> <td>Weight range</td> <td>30.0 – 50.0 kg</td> <td>50.1 – 70.0 kg</td> <td>≥70.1 kg</td> </tr> <tr> <td>Maximum recommended dose</td> <td>1,800 mg/day or 45 ml/day</td> <td>2,400 mg/day or 60 ml/day</td> <td>3,200 mg/day or 80 ml/day</td> </tr> </table> <p>Doses of up to 4,000 mg/day (100 ml/day) in the 30-50 kg range or 4,800 mg/day (120 ml/day) in the over 50 kg category have been studied in a limited number of patients.</p> <p><u>Discontinuation of treatment</u><br/>           When rufinamide treatment is to be discontinued, it should be withdrawn gradually. In clinical trials rufinamide discontinuation was achieved by reducing the dose by approximately 25% every two days. In the case of one or more missed doses, individualised clinical judgement is necessary. Uncontrolled open-label studies suggest sustained long-term efficacy, although no controlled study has been conducted for longer than three months.</p> <p><u>Paediatric population</u><br/>           The safety and efficacy of rufinamide of children aged 4 years and less have not yet been established. No data are available.</p> <p><u>Older people</u><br/>           There is limited information on the use of rufinamide in older people. Since, the pharmacokinetics of rufinamide are not altered in older people, dosage adjustment is not required in patients over 65 years of age.</p> |                                                                      |                           | Weight range | 30.0 – 50.0 kg | 50.1 – 70.0 kg | ≥70.1 kg | Maximum recommended dose | 1,800 mg/day or 45 ml/day | 2,400 mg/day or 60 ml/day | 3,200 mg/day or 80 ml/day |
| Weight range                                    | 30.0 – 50.0 kg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 50.1 – 70.0 kg                                                       | ≥70.1 kg                  |              |                |                |          |                          |                           |                           |                           |
| Maximum recommended dose                        | 1,800 mg/day or 45 ml/day                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 2,400 mg/day or 60 ml/day                                            | 3,200 mg/day or 80 ml/day |              |                |                |          |                          |                           |                           |                           |
| <b>Renal Impairment</b>                         | Mild<br>Moderate<br>Severe                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | No dose adjustments are required                                     |                           |              |                |                |          |                          |                           |                           |                           |
| <b>Hepatic impairment</b>                       | Mild<br>Moderate<br>Severe                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Caution and careful dose titration is recommended<br>Not recommended |                           |              |                |                |          |                          |                           |                           |                           |
| <b>Contra-indications / Special precautions</b> | <a href="#">Please refer to SPC</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                      |                           |              |                |                |          |                          |                           |                           |                           |
| <b>Side Effects</b>                             | <a href="#">Please refer to SPC</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                      |                           |              |                |                |          |                          |                           |                           |                           |
| <b>Monitoring</b>                               | Hepatic function<br>ECG – monitor QT interval<br>Signs of suicidal ideation and behaviours                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                      |                           |              |                |                |          |                          |                           |                           |                           |
| <b>Drug Interactions</b>                        | <a href="#">Please refer to SPC</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                      |                           |              |                |                |          |                          |                           |                           |                           |

Please note the information included in this document is correct at the time of writing. The manufacturer's Summary of Product Characteristics (SPC) and the most current edition of the British National Formulary should be consulted for up to date and more detailed prescribing information.

### References

[Rufinamide SmPC](#)

Rufinamide BNF

[NICE CG 137 - Epilepsy: diagnosis and management](#)

**Appendix 1:**

**Effective Shared Care Agreement (ESCA)**

**Rufinamide**

For the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years of age and older

Please refer to BSSE APC formulary website for complete document.

**BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)**

|       |                  |               |                |
|-------|------------------|---------------|----------------|
| Trust | Contact details  | Telephone No. | Email address: |
|       | Consultant:-     |               |                |
|       | Specialist Nurse |               |                |

| Patient's name | Date of birth | Sex | Home Address | Hospital Number |
|----------------|---------------|-----|--------------|-----------------|
|                |               |     |              |                 |
|                |               |     |              | NHS Number      |
|                |               |     |              |                 |

*Hospital Specialist/Consultant*

Name (please print) \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

**To be completed by the General Practitioner:**

I agree to participate in this shared care agreement for the treatment of the below named patient with *(drug name)* for *(indication)*

*General Practitioner*

Name (please print) \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

**Please keep a copy of this agreement for your own records and forward the original to the above named Consultant.**

| In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement. |           |                         |                       |           |             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-------------------------|-----------------------|-----------|-------------|
| GP Prescribing System                                                                                                                               | Read Code | Description             | GP Prescribing System | Read Code | Description |
| EMIS and Vision                                                                                                                                     | 8BM5.00   | Shared care prescribing | SystemOne             | XaB58     | Shared care |