Guidance for the Use of Pregabalin for the Treatment of Generalised Anxiety Disorder, (GAD), in Adults. (June 2015)

1. Indication

Use of pregabalin by Trust prescribers must be in line with its Product Licence and in line with NICE Clinical Guidance, (see below). Pregabalin is licensed for generalised anxiety disorder in adults, (and also for seizures and neuropathic pain). The product must not be prescribed for any other psychiatric disorders.

For the treatment of GAD, pregabalin must always be prescribed by generic name.

2. Place in Treatment

Wherever possible, NICE guidance for the treatment of GAD must be followed. In summary this makes the following recommendations for drug therapy:

1. First-line: A generic SSRI. (Including those not licensed for GAD, eg. sertraline)
2. Second-line: An alternative SSRI or an SNRI.
3. Third-line: Pregabalin – if SSRIs and/or SNRI are ineffective or not tolerated.

3. Process

Pregabalin is included in the Trust Formulary and may be prescribed in both inpatient and outpatient settings.

4. Dose Recommendations. (Patients 18 years of age and older).

Treatment should normally commence at 150mg daily in two divided doses. Based on response and tolerability, the dose can be increased to 300mg per day (in two divided doses) after a period of 7 days. Further dose increases may take place at 7-day intervals to 450mg daily and then, if absolutely necessary, to the maximum dose of 600mg daily. However, doses above 450mg must be kept under close review as some studies have shown no increased efficacy at higher doses.

All daily doses should be given in two divided doses (BD regime) unless there is compelling clinical reason to use a TDS regime, (see section 9, Pricing). Treatment response, tolerability and dosage must be re-assessed regularly and any discontinuation of the drug should take place gradually over the course of at least one week.

If you require this document in an alternative format, ie, easy read, large text, audio, Braille or a community language please contact the Pharmacy Team on 01243 623349. (Text Relay calls welcome)
5. Prescribing in Special Populations.

5.1 Pregabalin should not be used in children or adolescents due to insufficient safety data.
5.2 Pregabalin should not be used in pregnancy or during breast-feeding due to insufficient safety data.
5.3 The elderly will require reduced dosage if they have impaired renal function. (See below).
5.4 There is no requirement to reduce dosage in patients with hepatic impairment.
5.5 Pregabalin dosage must be adjusted in patients with impaired renal function. (See below).
5.6 Pregabalin should be avoided in patients with a recent history of drug misuse.

Pregabalin dosage based on renal function:

<table>
<thead>
<tr>
<th>Creatinine Clearance (mg / min)</th>
<th>Starting Dose (mg / day)</th>
<th>Maximum Dose (mg / day)</th>
<th>Dosage Regime</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 or above</td>
<td>150</td>
<td>600</td>
<td>BD (avoid TDS)</td>
</tr>
<tr>
<td>Between 30 and 59</td>
<td>75</td>
<td>300</td>
<td>BD (avoid TDS)</td>
</tr>
<tr>
<td>Between 15 and 29</td>
<td>25 - 50</td>
<td>150</td>
<td>BD or OD</td>
</tr>
<tr>
<td>Less than 15</td>
<td>25</td>
<td>75</td>
<td>OD</td>
</tr>
</tbody>
</table>

6. Medication Review

Pregabalin (and other medication prescribed for GAD) should be reviewed for effectiveness and side effects at least every 2-4 weeks during the first 3 months of treatment and at least every 3 months thereafter. Normally, effective treatment will be required for at least 12 months as risk of relapse is high.

7. Side Effects

7.1 Dizziness, somnolence and headache are reported as very common (>1 in 10).

7.2 The following have all been reported as common (>1 in 100, <1 in 10): increased appetite, weight gain, euphoria, confusion, disorientation, memory impairment, amnesia, insomnia, lethargy, irritability, decreased libido, erectile dysfunction, ataxia, gait abnormalities, balance disturbance, falls, tremor, dysarthria, attention disturbance, paraesthesia, blurred vision, diplopia, vertigo, nausea, vomiting, dry mouth, constipation, diarrhoea, abdominal distension, flatulence, feeling drunk, fatigue, peripheral oedema, nasopharyngitis, arthralgia, back pain, limb pain, muscle cramp, cervical spasm.

8. Caution in Use. (See also section 5 above).

8.1 The elderly may be at increased risk of falls due to the potential for pregabalin to cause somnolence, dizziness and ataxia. Also, there have been reports of elderly patients with cardiovascular disease developing congestive heart failure while on the drug.

8.2 Suicidal ideation / behaviour have been reported in patients treated with anti-epileptic drugs

8.3 The abuse potential of pregabalin is well documented, especially in prison populations. Caution should be exercised in all patients with a history of substance misuse and patients should be monitored for symptoms of pregabalin abuse.
8.4 A withdrawal syndrome has been observed in some patients. Symptoms include insomnia, nausea, diarrhoea, flu-like affects, nervousness, depression, sweating, dizziness and pain. Therefore abrupt discontinuation should be avoided. Dose tapering and withdrawal should take place over a period of at least seven days, (often much longer), whenever possible, especially after long-term treatment.

9. Significant Drug Interactions

9.1 Pregabalin has been reported to potentiate the effects of alcohol, lorazepam and oxycodone and concomitant use should be avoided wherever possible.

9.2 Pregabalin may also potentiate the effects of other CNS depressants.


Pregabalin is very expensive when compared to other treatments commonly used for the treatment of GAD.

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Paroxetine</td>
<td>Yes</td>
<td>20-30mg OD</td>
<td>£2</td>
</tr>
<tr>
<td>Escitalopram</td>
<td>Yes</td>
<td>10-20mg OD</td>
<td>£2</td>
</tr>
<tr>
<td>Citalopram</td>
<td>No</td>
<td>20-40mg OD</td>
<td>£1</td>
</tr>
<tr>
<td>Sertraline</td>
<td>No</td>
<td>50-200mg OD</td>
<td>£2 - £3</td>
</tr>
<tr>
<td>Duloxetine</td>
<td>Yes</td>
<td>30-60mg OD</td>
<td>£23 - £28</td>
</tr>
<tr>
<td>Venlafaxine XL</td>
<td>Yes</td>
<td>75-225mg OD</td>
<td>£11 - £32 (XL tablets)</td>
</tr>
<tr>
<td>Pregabalin</td>
<td>Yes</td>
<td>75-300mg BD#</td>
<td>£64</td>
</tr>
</tbody>
</table>

# Pregabalin has a flat pricing structure. Prescribing the same daily dose in a TDS regime will increase costs by 50%.

11. References


This document provides only summary guidance for the use of pregabalin in generalised anxiety disorder. Please refer to the BNF and to the Summary of Product Characteristics (for Lyrica®) for more detailed prescribing and safety information.

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Approved by Drugs & Therapeutics Group: July 2012.
Reviewed & updated: June 2015.
Date of next scheduled review: June 2018.