Effective Shared Care Agreement (ESCA)

Ropinirole (Adartrel®)

ESCA: For the treatment of restless legs syndrome

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of ropinirole for restless legs syndrome can be shared between the specialist and general practitioner (GP). You are invited to participate however, if you do not feel confident 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 restless legs syndrome 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 restless legs 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 ropinirole
5. Initiate treatment and stabilise dose of ropinirole
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 ropinirole 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		SystmOne	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 ropinirole with the specialist, clinical nurse specialist or GP
3. Report any adverse effects to the specialist or GP whilst taking ropinirole
4. Attend regular outpatient appointments with the specialist

BACK-UP ADVICE AND SUPPORT

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

Based on MTRAC template
Prepared by Satnaam Singh Nandra
Interface Lead Pharmacist
Birmingham CrossCity CCG

SUPPORTING INFORMATION

<table>
<tr><td>Indication</td><td colspan="2">Symptomatic treatment of moderate to severe idiopathic restless legs syndrome</td></tr>
<tr><td rowspan="3">Dosage and Administration</td><td>Treatment initiation (Week 1)</td><td>The recommended initial dose is 0.25 mg once daily, administered just before bedtime, however the dose can be taken up to 3 hours before retiring for 2 days. If this dose is well tolerated the dose should be increased to 0.5 mg once daily for the remainder of week 1.
<table>
<tr><td></td><td>Days</td><td>Week</td></tr>
<tr><td></td><td>1-2</td><td>1</td></tr>
<tr><td>Total daily dose (mg) of ropinirole</td><td>0.25</td><td>0.5</td></tr>
</table></td></tr>
<tr><td>Therapeutic regimen (Week 2 onwards)</td><td>Following treatment initiation, the daily dose should be increased until optimal therapeutic response is achieved. The average dose in clinical trials, in patients with moderate to severe restless legs syndrome, was 2.0 mg once a day.
The dose may be increased to 1.0 mg once a day at week 2. The dose may then be increased by 0.5 mg per week over the next two weeks to a dose of 2.0 mg once a day. In some patients, to achieve optimal improvement, the dose may be increased gradually up to a maximum of 4.0 mg once a day.
<table>
<tr><td></td><td colspan="6">Week</td></tr>
<tr><td></td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td></tr>
<tr><td>Total daily dose (mg) of ropinirole</td><td>1.0</td><td>1.5</td><td>2.0</td><td>2.5</td><td>3.0</td><td>4.0</td></tr>
</table></td></tr>
<tr><td colspan="2">The efficacy of ropinirole treatment has not been shown beyond 12 weeks. Patient response should be evaluated after 12 weeks treatment and the need for treatment continuation reconsidered. If treatment is interrupted for more than a few days it should be re-initiated by dose titration as noted above.</td></tr>
<tr><td rowspan="3">Renal Impairment</td><td>Mild - Moderate (creatinine clearance between 30 and 50 ml/min)</td><td>No dosage adjustment is necessary</td></tr>
<tr><td>End stage renal disease (patients on haemodialysis)</td><td>A dose adjustment is required as follows: the recommended initial dose of ropinirole is 0.25 mg once daily. Further dose escalations should be based on tolerability and efficacy. The recommended maximum dose is 3 mg/day in patients receiving regular haemodialysis. Supplemental doses after haemodialysis are not required</td></tr>
<tr><td>Severe (creatinine clearance less than 30 ml/min)</td><td>The use of ropinirole in patients with severe renal impairment without regular haemodialysis has not been studied.</td></tr>
<tr><td>Hepatic impairment</td><td colspan="2">Ropinirole should be administered with caution to patients with moderate hepatic impairment. Undesirable effects should be closely monitored.</td></tr>
<tr><td>Contra-indications / Special precautions</td><td colspan="2">Contraindication:-
Hypersensitivity to the active substance or to any of the excipients.
Severe renal impairment (creatinine clearance < 30 ml/min).
Severe hepatic impairment.
Ropinirole should not be used to treat neuroleptic akathisia, tasikinesia (neuroleptic-induced compulsive tendency to walk), or secondary restless legs syndrome (e.g. caused by renal failure, iron deficiency anaemia or pregnancy).
It is recommended that ropinirole is not used during pregnancy unless the potential benefit to the patient outweighs the potential risk to the foetus.
Ropinirole should not be used in nursing mothers as it may inhibit lactation
Cautions:-
Paradoxical worsening of restless legs syndrome symptoms described as augmentation (either earlier onset, increased intensity, or spread of symptoms to previously unaffected limbs), or early morning rebound (reoccurrence of symptoms in the early morning hours), have been observed during treatment with ropinirole. If this occurs, the adequacy of ropinirole treatment should be reviewed and dosage adjustment or discontinuation of treatment may be considered.
In Parkinson's disease, ropinirole has been associated uncommonly with somnolence and episodes of sudden sleep onset however, in restless legs syndrome, this phenomenon is very rare. Nevertheless, patients must be informed of this phenomenon and advised to exercise caution while driving or operating machines during treatment with ropinirole. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. A reduction of dosage or termination of therapy may be considered.
Patients with major psychotic disorders should not be treated with dopamine agonists unless the potential benefits outweigh the risks.</td></tr>
<tr><td rowspan="2">Side Effects</td><td>Very common</td><td>Vomiting, nausea</td></tr>
<tr><td>Common</td><td>Nervousness, Syncope, somnolence, dizziness (including vertigo), abdominal pain, fatigue</td></tr>
<tr><td>Monitoring</td><td colspan="2">Renal function
Liver function
Sudden onset of sleep and somnolence
Blood pressure
INR monitoring</td></tr>
</table>

Drug Interactions	**Ropinirole** has the following interaction information:

Antipsychotics	manufacturer of ropinirole advises avoid concomitant use of antipsychotics (antagonism of effect) **Note:** Increased risk of toxicity with myelosuppressive drugs
Ciprofloxacin	metabolism of ropinirole inhibited by ciprofloxacin (increased plasma concentration)
Metoclopramide	manufacturer of ropinirole advises avoid concomitant use of metoclopramide (antagonism of effect)
Oestrogens	plasma concentration of ropinirole increased by oestrogens

Ropinirole belongs to **Dopaminergics** and will have the following interactions:

Memantine	effects of dopaminergics possibly enhanced by memantine
Methyldopa	anti parkinsonian effect of dopaminergics antagonised by methyldopa

References

Adartrel SPC

Ropinirole BNF

I agree to participate in this shared care agreement for the treatment of the below named patient with ropinirole for restless legs syndrome.

General Practitioner

Name (please print)_____Signature _____Date_____

Hospital Specialist/Consultant

Name (please print)_____Signature_____Date_____

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

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