Effective Shared Care Agreement (ESCA)

Midodrine

ESCA: For the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of midodrine for the management of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate 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 severe orthostatic hypotension 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 severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate.
2. Consider midodrine • After non-pharmacological intervention - increased fluids (excluding decaffeinated drinks) and salt and the introduction of simple physical counter-pressure manoeuvres plus wearing support hosiery. and • Second line pharmacological therapy (Fludrocortisone is routinely used as first line drug therapy). i.e. midodrine is third line option in line with licensing.
3. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
4. 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.
5. Do baseline monitoring prior to initiation of midodrine (supine and standing blood pressure, manual active stand test (MAST), urea and electrolyte, renal function, liver function, thyroid function, eye examination (if clinically indicated based on patient's history regarding any vision or ocular problems using explicit questions regarding recent eye tests and any history of glaucoma or diabetic retinopathy). Where indicated a Heads Up Tilt Test (HUTT) is also organised as a one-off investigation.
6. **Before midodrine is prescribed** re-evaluate patient's clinical status, medication history and allergies. In addition (where relevant) pregnancy status is verbally established.
7. Initiate midodrine treatment on a two week trial; assess progress at a two week follow-up call. At this consultation both tolerance and symptom improvement are discussed, and if a positive outcome (i.e. patient is stable and responding well to midodrine) a 90 day prescription of midodrine is actioned, and consider transfer to primary care
8. Review the patient's condition and monitor response to treatment regularly – **annually - appropriate in most cases** However an earlier review would be required when: 1. Symptom deterioration continues despite medication modifications. 2. The daily dose exceeds 30mg i.e. above total daily recommended dose. 3. Symptoms change, indicating orthostatic hypotension is not the primary cause.
9. Send a written summary promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay.
10. Report serious adverse events to the MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
11. Ensure clear backup arrangements exist for GPs, for advice and support.

General Practitioner responsibilities
1. Following confirmation of dose stabilisation (after 2 weeks), consider the shared care request.
2. Document in patient's notes the non-pharmacological intervention and second line pharmacological therapy that has been tried. (Midodrine is a 3rd line option)
3. Reply to the request for shared care as soon as practicable i.e. within 10 working days.
4. Prescribe midodrine at the dose recommended.
5. 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

6. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist.
7. 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.
8. Refer back to specialist **for an annual review** or if :
   - Symptom deterioration continues despite medication modifications.
   - The daily dose exceeds 30mg i.e. above total daily recommended dose.
   - Symptoms change, indicating orthostatic hypotension is not the primary cause.
9. Report serious adverse events to specialist and MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
10. Stop treatment on the 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 midodrine with the specialist, clinical nurse specialist or GP.
3. Report any adverse effects to the specialist or GP whilst taking midodrine.
4. Attend regular outpatient appointments with the specialist, at least annually.

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

SUPPORTING INFORMATION

Indication	Severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate.
Dosage and Administration	Initial dose: 2.5 mg three times a day. Depending on the results of supine and standing blood pressure recordings, this dose may be increased weekly up to a dose of 10 mg three times a day. This is the usual maintenance dosage. A careful evaluation of the response to treatment and of the overall balance of the expected benefits and risks needs to be undertaken before any dose increase and advice to continue therapy for long periods. **The last daily dose should be taken at least 4 hours before bedtime in order to prevent supine hypertension.** Midodrine tablets may be taken with food.
Renal Impairment	There are no specific studies that have focused on a possible dose reduction in patients with renal impairment. Typically, midodrine is contraindicated in patients with acute renal impairment and severe renal impairment.
Hepatic impairment	There are no specific studies in this patient population.
Contra-indications / Special precautions	**Contraindications:-** • Severe organic heart disease (e.g. bradycardia, heart attack, congestive heart failure, cardiac conduction disturbances or aortic aneurysm). • Hypertension. • Serious obliterative blood vessel disease, cerebrovascular occlusions and vessel spasms. • Acute kidney disease. • Severe renal impairment (creatinine clearance of less than 30 mL/min). • Serious prostate disorder. • Urinary retention. • Proliferative diabetic retinopathy. • Pheochromocytoma. • Hyperthyroidism. • Narrow angle glaucoma. • Hypersensitivity to the active substance or to any of the excipients listed. **Cautions:-** Please see drug interactions section below.
Side Effects	Very common: Piloerection (goosebumps), pruritus of the scalp, dysuria. Common: Paraesthesia, paraesthesia of the scalp, headache, supine hypertension (dose dependent effect), nausea, dyspepsia, stomatitis, pruritus, chills, flushing, rash.

Monitoring parameter		Frequency			Action to be taken
		Baseline	**At dose change**	**On-going**	
ECG	**Bradycardia**	**Y**	**Y**	**Y, Annually**	**If signs or symptoms suggesting bradycardia – contact specialist**
Blood pressure	**Hypertension in the supine position**	**Y**	**Y**	**Y**	**The risk of supine hypertension occurring during the night can be reduced by elevating the head. If still not controlled – contact specialist.**
Renal function	**Acute kidney disease**	**Y**	**Y**	**Y, Annually**	**If creatinine clearance of less than 30 mL/min, stop treatment and contact specialist.**
Liver function		**Y**	**Y**	**Y, Annually**	**If abnormal hepatic function/raised liver enzymes - contact specialist.**
Eye examination	**Narrow angle glaucoma Proliferative diabetic retinopathy**	**Y**	**Y**	**Y, Annually**	**If raised IOP – contact specialist. If any retina and macular concerns – contact specialist.**
Thyroid function	**Hyperthyroidism**	**Y**	**Y**	**Y, Annually**	**If raised thyroid-stimulating hormone (TSH) levels – contact specialist.**
PSA	**Prostate disorder**	**Y**	**Y**	**Y, Annually**	**If raised PSA levels – contact specialist.**

Drug interactions	Sympathomimetics and other vasopressor agents (reserpine, guanethidine, tricyclic antidepressants, antihistamines, thyroid hormones and MAO-inhibitors)	Concomitant treatment with sympathomimetics and other vasoconstrictive substances should be avoided as a pronounced increase in blood pressure may occur.
	Alpha-adrenergic antagonists such as prazosin and phentolamine	The effect of midodrine is blocked by α- adrenergic antagonists.
	Glycosides	Simultaneous use of digitalis preparations is not recommended, as the heart rate reducing effect may be potentiated by midodrine and heart block may occur.
	Heart rate reducing drugs	Monitoring is recommended if midodrine is combined with other drugs that directly or indirectly reduce the heart rate.
	Corticosteroid preparations	Midodrine may potentiate or enhance the hypertensive effects of corticosteroid preparations. Patients being treated with midodrine in combination with mineralocorticoids or glucocorticoids (e.g. fludrocortisone) may be at increased risk of glaucoma/increased intraocular pressure, and should be carefully monitored.
	Potential pharmacokinetic interactions	Decreased clearance of medicinal products metabolised by CYP2D6 (e.g. promethazine) has been reported.

Reference

Midodrine (Bramox®) SmPC

Appendix 1:

Effective Shared Care Agreement (ESCA)
Midodrine (Bramox®)

For the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate.

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 above named patient with midodrine (Bramox®) for the management of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate.

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		SystmOne	XaB58	Shared care