

SPECIALIST INITIATION GUIDANCE

With additional information

Phenelzine for depressed patients clinically characterised as 'atypical', 'non endogenous', 'neurotic' or where treatment with other antidepressants has failed in adult services

WY ICS definition for specialist initiation:

Items initiated by a specialist that offer a valuable alternative/addition to the patients' treatment. These are considered suitable for GP prescribing following specialist initiation, including initial titration of dose and assessment of efficacy (where appropriate). The specialist will highlight if there is any need for any further titration. Some standard/routine monitoring may be required. Dosing will be in line with the BNF/SPC or outlined in the letter from the specialist. A brief prescribing document may be available otherwise this will just link to a standard document that outlines the responsibilities of the specialist, primary care prescriber and patient. All patients on these should still be regularly reviewed in primary care regarding their treatment.

We have started your patient on phenelzine for depression clinically characterised as 'atypical', 'non endogenous', 'neurotic' or where treatment with other antidepressants has failed. We will continue to see the patient and prescribe phenelzine for (minimum period of 8 weeks). After this period the General Practitioner (GP) /Primary Care Prescriber will be asked to take over prescribing, adjusting doses as recommended by the specialist, and monitoring.

Unless otherwise specified within this guidance, this drug must be initiated by a specialist who must be a prescriber with relevant expertise. Specialist may include consultants, registrars, GPs with special interest or independent non-medical prescribers with relevant experience/expertise. Subsequent changes in drug treatment may be recommended by non-prescribers with the relevant competency working with the specialist MDT in accordance with clinical guidelines and best practice

Indications (Please state whether licensed or unlicensed or unlicensed use of a licensed product)	<p>Phenelzine is a monoamine oxidase inhibitor (MAOI). It has been found to be effective in depressed patients clinically characterised as 'atypical', 'non endogenous', 'neurotic' or where treatment with other antidepressants has failed. These patients often have mixed anxiety and depression and phobic or hypochondriacal features. There is less conclusive evidence of its usefulness with severely depressed patients with endogenous features.</p> <p>This is a licensed use of the product.</p>
Initiation and ongoing dose regime	<p>One 15 mg tablet three times a day. A response is usually seen within the first week. If no response is evident after two weeks, the dosage may be increased to a maximum of one 15mg tablet four times a day. Doses of up to two 15mg tablets three times a day may be used in hospitals. The effectiveness of the drug may not become apparent in less than 4 weeks therapy. After a satisfactory response has been achieved, the dosage may be reduced very gradually to a suitable maintenance level. This may be as low as one 15mg tablet every other day.</p>

Pharmaceutical aspects If a medicine needs to be prescribed by brand /formulation information will be included in this section.	Route of administration:	Oral	
	Other important information:	Phenelzine should be prescribed as the sole antidepressant. Combination with other antidepressants, even when prescribed for other indications, can cause significant risk of harm. Use with some antidepressants is contraindicated by the product licence.	
Baseline investigations, routine tests/monitoring and follow up	Baseline investigations: <ul style="list-style-type: none">Monitoring at baseline is the responsibility of the specialist.No routine monitoring is required by the product licence but liver function, full blood count and blood pressure are recommended at baseline. Routine tests/ monitoring: <ul style="list-style-type: none">No routine monitoring is required by the product licence but liver function, full blood count and blood pressure are recommended if indicated by clinical presentation. Blood pressure should be checked annually to detect any pressor response and therapy discontinued if palpitations or frequent headaches occur. <p>Patients should be asked to report symptoms of postural hypotension. Routine disease monitoring should continue.</p> <p>Follow up: On an individual basis, details will be included in the care plan.</p>		
	Consult the BNF, and SPC for full and current prescribing information. <i>The following information has been added only if it differs from the BNF, BNFC and SPC or supports that information. Only add to sections A - E below- if additional or different information to standard resources, if not remove these sections</i>		
B. Significant medicine interactions	Link to SPC Information about the risks of interaction with tyramine containing foods must be provided - Link		
C. Adverse effects and management This section will be removed if licensed medicine. For unlicensed medicines then information would be added. Where relevant add information regarding at what point GPs/Primary Care Prescribers should refer back to the specialist or note that this should be managed in line with usual Primary Care practice.	Result	Action for GP/Primary Care Prescriber	
	Abnormal liver function	Phenelzine is contraindicated in patients with abnormal liver function. Discuss alternative treatment options with the specialist.	
	Abnormal full blood count	Discuss alternative treatment options with the specialist	
	Abnormal blood pressure	Postural hypotension, offer advice and refer back to specialist if persistent Hypertension in association with other symptoms of hypertensive crisis discontinue and advise attendance at emergency department	

	<p>Other adverse effects should be managed in line with usual Primary Care practice.</p> <p>Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme www.mhra.gov.uk/yellowcard</p>
<p>D. Advice to patients and carers</p> <p>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.</p>	<p>The patient should be advised to report any of the following signs or symptoms to their GP/Primary Care Prescriber without delay:</p> <p>If you take an MAOI and eat or drink anything containing tyramine, it can cause a rapid rise in your blood pressure. This reaction can occur within an hour or two. The signs of a reaction include:</p> <ul style="list-style-type: none"> • Headache (especially at the back of the head) • Pounding of the heart • Light-headedness or dizziness • Flushing of the face • Numbness or tingling of the hands or feet • Pain or stiffness in the neck • Feeling sick and/or being sick. <p>If any of these occur, especially after eating or drinking, taking other medicines or if unexpected or severe, go to the casualty department at your nearest hospital. This is so you can be checked over and you can be given any urgent treatment needed to bring your blood pressure under control.</p> <p>Further information can be found on the choice and medication links below</p>
<p>E. Pregnancy, paternal exposure, and breast feeding</p> <p>It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation but the ongoing responsibility for providing this advice rests with both the GP/Primary Care Prescriber and the Specialist.</p>	<p>Link to SPC</p> <p><u>Pregnancy:</u> Limited Human Data—Animal Data Suggest Moderate Risk</p> <p><u>Breastfeeding:</u> No Human Data—Potential Toxicity</p> <p>The most common adverse reactions in adults were dizziness, headache, drowsiness, sleep disturbances, fatigue, weakness, tremors, twitching, myoclonic movements, hyperreflexia, constipation, dry mouth, and oedema. If a woman is receiving this drug while breastfeeding, her nursing infant should be monitored for these effects.</p>
<p>Specialist contact information</p>	<p>See specialist letter for details</p> <p>Bradford District Care NHS Foundation Trust phone number and e-mail: 01274 363 230 pharmacy@bdct.nhs.uk</p>

	<p>Calderdale and Kirklees NHS Foundation Trust phone number and e-mail: 01484 343108 or 01422 222933 PharmacyteamCK@swyt.nhs.uk</p> <p>Leeds and York Partnership Foundation Trust phone number and e-mail: 0113 8555534 Pharmacyleedsptf.lypft@nhs.net</p> <p>South West Yorkshire Partnership NHS Foundation Trust For Wakefield FieldheadPharmacy@SWYT.nhs.uk 01924 316820</p>
To be read in conjunction with the following documents	<p>Depression in adults: treatment and management https://www.nice.org.uk/guidance/ng222</p> <p>Depression in adults with a chronic physical health problem: recognition and management https://www.nice.org.uk/guidance/cg91</p> <p>Social anxiety disorder: recognition, assessment, and treatment https://www.nice.org.uk/guidance/cg159</p>
Specialist responsibilities	<ul style="list-style-type: none"> • Ensure current diagnosis of condition and the treatment options have been discussed and understood by the patient (and their carers where appropriate). • To assess the suitability of the patient for this treatment. • To discuss the benefits and side effects of treatment with the patient/carer and where applicable the need for long term monitoring. • Provide detailed verbal and written advice on interactions with foods containing tyramine. • Checking for allergies, interactions, and contra-indications. • To perform baseline tests, to initiate treatment in agreement with the patient/carer. • To assess and monitor the patient's response to treatment (as appropriate) and when safe to do so transfer prescribing to the GP/Primary Care Prescriber. • Liaise with the patient's GP/Primary Care Prescriber whether they are willing to take over the prescribing and monitoring responsibilities under this specialist initiation guidance. • To advise on the dose to be prescribed and any dose adjustments appropriate. • To advise GP/Primary Care Prescriber what routine monitoring will be completed by the specialist and what monitoring the GP/Primary Care Prescriber will be responsible for. • To forward results of monitoring to GP/Primary Care Prescriber. • Advise when therapy may be reduced and stopped assuming no relapse in patient's condition. Review periods to be agreed. • Ensure this is also known, understood, and agreed with the patient (and where appropriate their carers). • Responding to issues raised by GP/Primary Care Prescriber and informing the patient (and carers) of any changes. • To monitor the patient for adverse events/side effects and report to the GP/Primary Care Prescriber and where appropriate Commission

	<p>on Human Medicines/MHRA (Yellow card scheme).</p> <ul style="list-style-type: none"> • Discuss with the patient their responsibilities outlined below, confirm understanding, and confirm that the patient is happy to adhere to them.
Primary Care prescriber responsibilities	<ul style="list-style-type: none"> • Checking for allergies, interactions and contra-indications when taking over prescribing and when changing treatment or initiating new treatments. • To prescribe Phenelzine and adjust the dose as recommended by the specialist following initiation and stabilisation by the specialist. • Monitoring the patient's overall health and wellbeing, observing patient for evidence of ADRs and liaising with specialist clinician if necessary and where appropriate report to Commission on Human Medicines/MHRA (Yellow card scheme). • Routine disease or condition monitoring should continue. • When patient attends for review of treatment confirm, in line with the information already provided, by the specialist (or other specialist acting on their behalf) the circumstances under which the medicines should be immediately stopped and what actions the patient is to take. • To ensure that there is an agreed process in place for accessing the ongoing supply of the medicines that is not placing any unnecessary burden or workload on the patient or their carers. Prescriptions should be issued and dispensed following usual processes. • Ensure advice is sought from the responsible specialist clinician if there is any significant change in the patient's physical or mental health status that may affect prescribing or appropriateness of the medicine, or any information relevant to their care that becomes available that was not made available at the time of the specialist diagnosis and treatment option agreement. • Take reasonable steps to ensure that the patient is using their medicines as prescribed and intended. • Reducing/stopping treatment in line with specialist clinician's original request • Encourage the patient at medication review appointments to ask questions and raise any concerns they have about their treatment, particularly anything that may be affecting their adherence to treatment. Use the Me & My Medicines Charter - https://meandmymedicines.org.uk/the-charter/.

Patient/carer responsibilities	<ul style="list-style-type: none"> • To agree and accept responsibility for taking Phenelzine as prescribed. • To understand how to take Phenelzine safely. • To understand the most common adverse events/side effects and inform the Specialist/ GP/Primary Care Prescriber as soon as reasonably possible should they occur and significantly affect the use of the medicines. • To understand the circumstances under which the medicines should be immediately stopped and what action to take. • The duration of treatment prescribed initially by the hospital specialist should be understood. • To attend for blood tests/disease monitoring on time. • To check with the community pharmacist that there are no interactions with phenelzine, and other medications taken including other prescribed medications, medicines bought over the counter and herbal/homoeopathic products. • To check with dentists or other specialists who may prescribe medicines that there are no interactions with phenelzine. • To understand contents of written information provided by the Specialist and in the patient information leaflet supplied with the medicines and to seek clarification if required. • To contact the GP/Primary Care Prescriber, Specialist or Medicines Information patient helpline if further information or advice is needed about this medication or if there is anything they do not understand. • More information on asking about medication can be found in the Me & My Medicines Charter https://meandmymedicines.org.uk/the-charter/. <p>The NHS Website information on health link and medicines link</p> <p>Patient information leaflets for mental health conditions and treatments:</p> <p>Leeds and York Partnership NHS Foundation Trust www.choiceandmedication.org/leedsandyorkpft</p> <p>South West Yorkshire Partnership NHS Foundation Trust www.choiceandmedication.org/swyp/</p> <p>Bradford District Care NHS Foundation Trust www.choiceandmedication.org/bradford</p>
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