June 2020



Phenelzine (NardilTM) tablets – supply issue update

The sole UK manufacturer of phenelzine has been out of stock for several months and now have no date for a return of supply. Unlicensed imports were being used, however, as supplies are becoming depleted in other countries, importing companies can no longer reliably obtain phenelzine from abroad in a timely manner.

It is now possible to obtain a UK unlicensed special. It is currently unclear whether this supply will be sustained in the longer term. Further guidance will be issued if it becomes necessary.

Guidance and recommendations to prescribers

Phenelzine is an irreversible monoamine oxidase inhibitor (MAOI) and is the preferred first line MAOI on our formulary. Patients treated with phenelzine will usually have tried several other antidepressants in the past and will require ongoing treatment with this medicine to prevent relapse. Treatment should not be stopped abruptly. Ensuring patients can continue to obtain a supply of this medicine is extremely important.

OHFT has been made aware of a UK specials manufacturer that has formulated a phenelzine 15mg *capsule*. The manufacturer is a registered pharmaceutical manufacturer with an MHRA Manufacturer's Specials Licence.

The UK licensed product (Nardil™) and the phenelzine, licensed in the US and Canada, that have been imported for unlicensed use in the UK, were in *tablet* form.

OHFT has approved the prescribing of this specials product, where a clinical decision has been made that this would be in the best interest of the patient and where this decision has been discussed with the patient (and they agree) and documented in the Electronic Health Record (EHR).

Prescribers should:

- Not initiate phenelzine for any new patients.
- For existing patients, consider the appropriateness of either switching to an alternative antidepressant or continuing treatment with an unlicensed special product.
- Discuss the use of an unlicensed special with the patient and document the decision in the EHR. Provide the patient with the information below.
- Any decision to prescribe an unlicensed medicine must take into account the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information. The use of this unlicensed special has been approved by OHFT and it is not necessary to complete any additional paperwork before prescribing.
 - Prescribing unlicensed medicines, General Medical Council (GMC),
 - The supply of unlicensed medicinal products, Medicines and Healthcare products
 Regulatory Agency
 - Professional Guidance for the Procurement and Supply of Specials Royal Pharmaceutical Society
- Indicate on the FP10 prescription that an unlicensed product is required. This can be done by annotating the prescription with the following wording: "special order".

MEDICINES SHORTAGE BULLETIN



- Provide <u>supporting information about unlicensed medication</u> as appropriate.
- Ensure the patient knows to expect that the product will be a *capsule* and not a tablet.
- Advise them to take the prescription to their local pharmacy in plenty of time before their
 existing supply runs out, as it may take a little longer than usual for the prescription to be
 fulfilled.
- Suggest that they take the information below to their local pharmacy in case it is useful for helping the pharmacist source this product.

It may be worthwhile providing the following information to the patient to take with them to their community pharmacist:



Dear Pharmacist,

This is a prescription for phenelzine 15mg *capsules*. There has been a long-term supply issue with the UK licensed phenelzine tablet (Nardil®) with no date for re-supply. The unlicensed imports, which have been available over the past year, and which you may have previously ordered, are becoming increasingly difficult to obtain.

Phenelzine 15mg capsules are an unlicensed specials product, available from a UK specials manufacturer that accepts orders placed by community pharmacies.

If you need any information about where to obtain this product, please contact Oxford Health NHS Foundation Trust's Medicines Advice Service on 01865 904365.

Many thanks.

Need more information/advice?



Please contact the Trust's Medicines Advice Service:

01865 904365 or medicines.advice@oxfordhealth.nhs.uk