

Shortage of Phenzelzine (Nardil®) 15mg tablets

Updated: 16th March 2020

Description of product affected

- Phenzelzine is a monoamine-oxidase inhibitor (MAOI) licensed for the treatment of depression.¹ It has been found to be effective in patients clinically characterised as 'atypical', 'non endogenous', 'neurotic' or where treatment with other antidepressants has failed.
- NICE supports the use of phenzelzine as an antidepressant and as an option in the treatment of social anxiety disorder.^{2,3} Phenzelzine is also used in patients with mixed depression and generalised anxiety disorder, panic disorder and post-traumatic stress disorder.⁴
- The recommended starting dose is 15mg three times daily which can be increased to four times a day if necessary.⁵ Doses of up to 30mg three times a day can be used in hospitalised patients. Once a satisfactory response has been achieved the dose can be reduced gradually to the lowest suitable maintenance dose.
- Phenzelzine may be associated with withdrawal effects if stopped suddenly. Although these are usually mild and self-limiting for some patients, withdrawal effects may be severe. It is advised that the dose should be reduced gradually over at least 4 weeks or longer if withdrawal symptoms emerge. Withdrawal over 6 months is recommended when patients have been taking it as a long-term treatment.
- When switching to an alternative antidepressant, it is advised to leave a 14-day washout period between stopping the phenzelzine and initiating the new treatment.^{4,6}

Background

- Kyowa Kirin are the sole supplier of phenzelzine tablets in the UK.
- **They are currently unable to advise a resupply date.**
- At present it seems possible to import supplies of unlicensed phenzelzine tablets whilst there is no stock available in the UK.

Alternative agents and management options

- Phenzelzine tends to only be used in difficult to treat patients and many of these have been stabilised on this treatment for a long time.
- Given the difficulties in withdrawing treatment and initiating new treatments in patients stabilised on phenzelzine it would seem advisable to maintain them on this treatment using imported supplies if necessary, which would need to be treated as an unlicensed medicine in line with local clinical governance procedures.

Urgent Action

For GP practices:

- **GP practices should urgently identify patients prescribed phenelzine 15mg tablets (including the brand Nardil)** to determine the quantity of stock that patients have remaining.
- Where patients do not have sufficient supplies, practices should liaise with pharmacies directly to ascertain their stock levels as different pharmacies use a range of wholesalers.
- Where an imported product is required to maintain the patients supply of phenelzine 15mg tablets, the prescription should be written in a time frame to allow the pharmacy to order the stock from the importing company before the patient runs out of medication in order to avoid abrupt withdrawal.
- **Ordering of imports may take much longer than the normal ordering process.**
- **In order to be reimbursed for a special order of phenelzine, the prescription must read Phenelzine 15mg tablets (special order).**
- **Prescriptions for the import should be written generically (Phenelzine 15mg tablets) and for whole packs quantities.** Our team have contacted all of the importers below and have confirmed that **each import pack contains 60 tablets.** Therefore, we would advise you to prescribe a clinically suitable quantity of tablets for your patients **in multiples of 60.**
- **Unlicensed imports can be obtained through normal wholesaler routes. However, if pharmacies are unable to obtain supplies, they are advised to contact specialist importer companies directly.**

The following specialist importer companies have advised that they can continue to source unlicensed imports from abroad.

- Clinigen via 01932 824100
- Target via 0845 618 0036
- Alium via 0208 238 6786
- Mawdsleys via 0844 736 9016
- Durbin via 0208 868 6500
- WEP Clinical via 0208 004 8185
- Waymade via 01268 535200, currently are supplying directly to Alliance HC.

- Different pharmacies use different wholesalers, and you should support the patient to find a pharmacy that can order the imported products.
- Counsel the patient and their carers as appropriate about any change to their medication, including where an imported brand may be required, BEFORE any change is made.

*An URGENT referral should be made to the patient's mental health specialist for advice **ONLY IF** imported phenelzine cannot be obtained within a sufficient timeframe within Primary Care.*

For pharmacies:

- Support by checking your current stock levels of these products and informing your local practices.
- Support by checking your pharmacy has an account with the importers listed above in preparation for when an order needs to be placed and keep up to date with the estimated delivery timescales with importer companies.
- Support GPs in counselling patients regarding any change to their medication, including any changes in packaging or appearance of tablets, which may be unusual to a patient.
- **In order to be reimbursed for a special order of phenelzine, the prescription must read Phenelzine 15mg tablets (special order).**
- Your payment will be based on your endorsement of **manufacturer, price, pack size, batch and license number**. You would also be able to **claim an addition fee of £20 by endorsing SP** on the prescription also.
- **Advise GPs that prescriptions for the import should be written generically** as Phenelzine 15mg tablets and for **whole packs quantities**. Our team have contacted all of the importers below and have confirmed that **each pack contains 60 tablets**.

References

1. Kyowa Kirin Ltd. Summary of Product Characteristics for Nardil tablets. Last updated Feb 2017. Available: <https://www.medicines.org.uk/emc/product/228>
2. NICE. Depression in adults: recognition and management. Clinical guideline [CG90] Published date: October 2009, last updated: April 2018. Available: <https://www.nice.org.uk/guidance/cg90>
3. NICE. Social anxiety disorder: recognition, assessment and treatment Clinical guideline [CG159] Published date: May 2013. Available: <https://www.nice.org.uk/guidance/cg159>
4. Taylor DM et al. The Maudsley Prescribing Guidelines in Psychiatry 13th edition. Published 2018. John Wiley & Sons Ltd.
5. British National Formulary. Phenelzine monograph. Accessed via Medicines Complete, last updated 11 June 2019. Available: <https://doi.org/10.18578/BNF.762962594>
6. UKMI Q&A. How do you switch between monoamine oxidase inhibitors and SSRI, tricyclic or related antidepressants? Published Nov 2015. Available: <https://www.sps.nhs.uk/wp-content/uploads/2015/12/NW-QA151.5-How-do-you-switch-between-MAOIs-and-SSRIs-TCAs-or-related-antidepressants-.pdf>

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