

Shortage of Phenzelzine (Nardil®) 15mg tablets

Updated: 10th July 2020

To be used in conjunction with the [CAS alert issued 03/07/2020](#).

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}

Current situation

- Kyowa Kirin are the sole supplier of licensed phenzelzine tablets in the UK.
- **Due to significant challenges, Kyowa Kirin are unable to continue to manufacture phenzelzine to supply the UK. There is currently no confirmed resupply date.**
- **Unlicensed imports of phenzelzine 15mg tablets were being used to manage patients and maintain treatment, however due to global supply issues these imports have become unreliable.**⁷ See table for importer companies that currently have the tablet formulation available.
- **Supplies of unlicensed phenzelzine 15mg capsule specials have become available.**⁷ Kyowa Kirin have supplied the Active

Pharmaceutical Ingredient (API) phenelzine to Target Healthcare UK Ltd. **Target Healthcare UK will be manufacturing and supplying a phenelzine capsule as an unlicensed special to the UK market.**⁸

Alternative agents and management options

- Phenelzine tends to only be used in patients that have not responded to treatment with other antidepressants and many of these have been stabilised on this treatment for a long time.
- It is clinically unsafe to stop or switch this drug abruptly, therefore, any switching or withdrawal will need to be undertaken by a specialist.
- Given the difficulties in withdrawing treatment and initiating new treatments in patients stabilized on phenelzine it would seem advisable to maintain these patients on this treatment using either the unlicensed imported supplies of phenelzine 15mg tablets or the unlicensed special phenelzine 15mg capsule formulation. Both of 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 and prior to the patient running out of their supplies.**
- **GPs should identify all patients prescribed phenelzine 15mg tablets and refer these patients for a specialist mental health review regarding ongoing management, whilst ensuring in the interim that patients have sufficient supplies.**
- Where patients have supplies of less than 4 weeks remaining, practices should liaise with their local pharmacies directly to ascertain their stock levels as different pharmacies use a range of wholesalers and specialist importers and may be able to obtain unlicensed phenelzine 15mg tablets as a specialist import or unlicensed phenelzine 15mg capsules as a special.
- Where local pharmacies do have supplies or are able to order supplies:
 - In order to be reimbursed for a special order of phenelzine, the prescription must read either Phenelzine 15mg tablets or capsules (special order) depending on the formulation that the pharmacy is able to obtain.
 - *Phenelzine 15mg capsules are not for selection on the GP clinical system and these will need to be prescribed using the 'free-text' box. Please note that prescriptions written in this way will not be able to be sent electronically therefore the original hard copy will need to be supplied to the dispensing pharmacy.*
 - Prescriptions for either formulation should be written generically and for whole packs quantities.
- **Where, local pharmacies do not have supplies we would ask you to alert our team directly regarding individual patients using our prescribing partnership mailbox CAPCCG.prescribingpartnership@nhs.net.**
- The Medicines Optimisation Team are monitoring the supply situation of phenelzine formulations extremely closely.

For Community Pharmacies and Dispensing Practices:

- Information has been received from the following specialist importers and manufacturers who may be able to support with obtaining supplies for patients (see table below).
- **Please can pharmacies/dispensing practices who dispense phenelzine 15mg tablets (brand name Nardil) to patients, who do not have an account setup with the specialist importer/companies listed below contact these directly to setup an account and place an order for the appropriate phenelzine 15mg formulation for your regular patients.**
- If you require further information or support from the Medicines Optimisation Team on this matter, please do not hesitate to contact us via our prescribing partnership mailbox: CAPCCG.prescribingpartnership@nhs.net.
- Where a capsule formulation is prescribed to a patient, in place of their usual tablet formulation, please could you support in counselling the individual patients, as applicable regarding the change of appearance and formulation.

Update from specialist importers (as of 25/06/2020):

Please note there may be other manufacturers/importers available to source phenelzine than those listed.

Importer	Telephone number	Phenelzine availability
Aclardian Limited	01954 213490	Stock available of phenelzine 15mg capsules available in pack sizes of 60. Ready for shipment direct to community pharmacies. <i>Please note prescriptions will need to be written as phenelzine 15mg capsules.</i>
Alium	020 8238 6770	Expecting to receive stock beginning of July 2020. Alium would advise placing a back order with themselves and you must have an account setup with Alium Medical. New accounts may be arranged.
Clinigen	01932 824100	Stock available and further stocks arriving over the coming weeks. Priority booking so once arrives Clinigen hope to get to Community Pharmacies/Dispensaries within 48 hours once it has been approved by their quality checks. Must have an account with this importer and have placed a back order.
Durbin	020 8869 6555	Durbin has 15mg tablets available in packs of 60 available and are expecting further stocks next week. For Community Pharmacies/Dispensaries without an account, new accounts can be arranged.
Mawdsleys	01302 553000	UK manufactured special being brought in within the next 2 weeks of phenelzine 15mg capsules. <i>Please note prescriptions will need to be written as phenelzine 15mg capsules.</i> It can take 2 days to setup an account so Community Pharmacies/Dispensaries should do this ASAP to setup a backorder. Next day delivery is available for CPs with an account.

Target	0845 618 0036	Target are manufacturing 15mg capsules in the UK and these are available to order. Please note prescriptions will need to be written as <i>phenelzine 15mg capsules</i> . Community Pharmacies/Dispensaries must have account with this importer and have placed a back order. Target have a next day delivery service for this product.
Waymade	01268 535200	No date on when will be available again.
WEP Clinical	0208 004 7318	Supplies will be available by end of next week w/e 05/07/2020. Community Pharmacies/Dispensaries must setup an account to place a back-order and this should be done ASAP. Once stock is available, WEP Clinical can deliver next day as required.

All of the above was personal correspondence between Cambridgeshire and Peterborough CCG Medicines Optimisation Team and the specialist importers.

*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 prior to the patient having their specialist review.*

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>
7. Department of Health and Social Care. Supply Disruption Alert. Issued 25 June 2020. Available: [SDA-2020-011.pdf](#)
8. Personal communication with Kyowa Kirin Ltd 25th June 2020.

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