NHS Circular: MSAN (2025) 17

Chief Medical Officer Directorate Pharmacy and Medicines Division



22 April 2025

Medicine Supply Alert Notice

Galantamine 8mg, 16mg and 24mg modified-release capsules

Priority: Level 2* Valid until: July 2025

Issue

- 1. Galantamine 8mg modified release capsules are in limited supply until late July 2025.
- 2. Galantamine 16mg modified release capsules will be out of stock from mid-April until late May 2025.
- 3. Galantamine 24mg modified release capsules will be out of stock from late April until late July 2025.
- 4. Galantamine 8mg, 16mg and 24mg tablets were discontinued and are no longer available.
- 5. Galantamine 20mg/5ml oral solution sugar free remains available and can support full increased demand.
- 6. Alternative solid dosage forms of acetylcholinesterase (AChE) inhibitors (donepezil tablets and rivastigmine capsules) remain available.
- 7. Unlicensed supplies of galantamine 8mg, 16mg and 24mg modified release capsules may be sourced, lead times vary.

Advice and Actions

- 8. Where individuals have insufficient supplies to last until the re-supply date, prescribers should:
 - consider maintaining the same treatment by prescribing galantamine 20mg/5ml oral solution sugar free which is able to support the market during this time, ensuring that the patient is not intolerant to any of the excipients and is counselled on the change in dosing schedule (see Additional information section);
 - consider prescribing unlicensed supplies of galantamine 8mg, 16mg and 24mg modified release capsules, only where licensed galantamine 20mg/5ml oral solution is not appropriate.
 Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see Additional information section); and
 - if the above options are not considered appropriate, seek advice from specialists on suitability
 of an alternative AChE inhibitor (see Additional information section) in solid dosage form
 (donepezil tablets or rivastigmine capsules).

Additional Information

Clinical Information

- 9. Galantamine, an AChE inhibitor, is licensed for the symptomatic treatment of mild to moderately severe dementia of the Alzheimer type.
- 10. When switching to galantamine oral solution, the same total daily dose of galantamine is administered but in two divided doses beginning the day after the last dose of modified-release capsules.

Table 1: Galantamine dosing

	Galantamine modified release capsule	Galantamine oral solution
Initial dose	8mg once daily in the morning, preferably with food for 4 weeks	4mg twice a day for four weeks, with morning and evening meals
Maintenance dose	16mg once daily for at least 4 weeks	8mg twice a day for at least 4 weeks
Maximum dose*	24mg once daily	12mg twice a day

^{*}Increase to a maintenance total daily dose of 24mg considered on an individual basis after appropriate assessment including evaluation of clinical benefit and tolerability.

Excipients

11. Galantamine oral solution contains the preservative(s) propyl parahydroxybenzoate and/ or methyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed). Some formulation may contain sorbitol which should not be taken by patients with hereditary fructose intolerance.

Table 2: NICE guidance

Guidance	Recommendation
Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (TA217)	AChE inhibitors, donepezil, galantamine and rivastigmine, as monotherapies are options for managing mild to moderate Alzheimer's disease. Treatment should normally be started with drug with lowest acquisition cost. However, an alternative AChE inhibitor could be prescribed if it is considered appropriate when taking into account adverse event profile, expectations about adherence, medical comorbidity, possibility of drug interactions and dosing profiles.
Dementia: assessment, management and support for people living with dementia and their carers (NG97)	Offer donepezil or rivastigmine to people with mild to moderate dementia with Lewy bodies. Only consider galantamine for people with mild to moderate dementia with Lewy bodies if donepezil and rivastigmine are not tolerated.

Parkinson's disease in adults (NG71)	Offer an AChE inhibitor for people with mild or moderate Parkinson's disease dementia (rivastigmine capsules are only treatment with UK marketing authorisation for this indication. Use of donepezil, galantamine and rivastigmine patches is offlabel).
	Consider an AChE inhibitor for people with severe Parkinson's disease dementia (off-label use).

Links to further information

BNF - Dementia

SmPC – Galantamine 8mg, 16mg and 24mg modified release capsules

SmPC – Galantamine 20mg/5ml oral solution

SmPC - Donepezil tablets

SmPC - Rivastigmine

Guidance on ordering and prescribing unlicensed imports

- 12. The following specialist importers have confirmed they can source unlicensed galantamine 8mg, 16mg or 24mg modified release capsules (please note there may be other companies that can also source supplies):
 - Alium Medical
 - Clinigen
 - QMed Pharma
 - Target Healthcare
- 13. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health Board local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes. Please see the links below for further information:
 - <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA)
 - <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society
 - Prescribing unlicensed medicines, General Medical Council (GMC).

Specialist Pharmacy Service (SPS) website

- 14. The UK Department of Health and Social Care (DHSC) in conjunction with Specialist Pharmacy Service (SPS) have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the SPS website. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 15. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues

will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

16. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or NSS.NHSSMedicineShortages@nhs.scot (secondary care).