

Department of Health & Social Care





MSN/2025/022

Galantamine 8mg, 16mg and 24mg modified-release capsules Tier 2 – medium impact* Date of issue: 11/04/2025 Link: <u>Medicines Supply Tool</u>

Summary

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

Actions Required

Where patients 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 Supporting information);
- 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 supporting information below); and
- if the above options are not considered appropriate, seek advice from specialists on suitability of an alternative AChE inhibitor (see Supporting information) in solid dosage form (donepezil tablets or rivastigmine capsules).

Supporting information

Clinical Information

Galantamine, an AChE inhibitor, is licensed for the symptomatic treatment of mild to moderately severe dementia of the Alzheimer type.

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

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 (<u>TA217</u>) | 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 (<u>NG97</u>) | 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 (<u>NG71</u>) | 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 off- label). Consider an AChE inhibitor for people with severe Parkinson's disease dementia (off-label use). |

Links to further information

<u>BNF – Dementia</u> <u>SmPC – Galantamine 8mg, 16mg and 24mg modified release capsules</u> <u>SmPC – Galantamine 20mg/5ml oral solution</u> <u>SmPC – Donepezil tablets</u> <u>SmPC- Rivastigmine</u>

Guidance on ordering and prescribing unlicensed imports

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

• QMed Pharma

Clinigen

• Target Healthcare

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or 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
- <u>Prescribing unlicensed medicines</u>, General Medical Council (GMC)

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:

- Galantamine 8mg modified release capsules (imported)
- Galantamine 16mg modified release capsules (imported)
- Galantamine 24mg modified release capsules (imported)

Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "**special order**".

Enquiries

If you have any queries, please contact <u>DHSCmedicinesupplyteam@dhsc.gov.uk.</u>