Interface Prescribing Subgroup
DRUGS FOR DEMENTIA: Galantamine
INFORMATION FOR PRIMARY CARE

RAG List Status

Cholinesterase inhibitors are classified as GREEN (following specialist initiation) drugs by the Greater Manchester Medicines Management Group.

Licensed Indications

Galantamine is licensed for the symptomatic treatment of patients with mild to moderately severe Alzheimer's disease.

NICE Guidance

NICE TA217 recommends that Acetylcholinesterase inhibitors are clinically cost effective and has recommended their use in mild to moderate Alzheimer's Disease.
NICE CG42 also recommends they be considered for people with dementia with Lewy bodies and patients with Alzheimer's Disease irrespective of severity who have non cognitive symptoms and/or behavioural challenges causing significant distress or potential harm to the individual.

Who will diagnose and decide who is suitable for which drug?

Specialists will continue to diagnose, assess suitability and safety of drug treatment for patients referred to Memory Services. Specialists will counsel and inform patients of their diagnosis and treatment options. Specialists will then follow up the patients until the patient is stable on the maximum tolerated dose of medication, this is usually for a period of one to three months.

Preparations available

8mg and 12mg tablets; 8mg, 16mg and 24mg prolonged release capsules; 4mg/ml oral solution

Dosage and Administration

The dose is initially 4mg twice daily for a minimum period of 4 weeks with a maintenance dose 8mg twice daily for a minimum of 4 weeks. This can be increased to 12mg twice daily after appropriate assessment of benefit & tolerability.
If no response to the higher dose or unable to tolerate, reduce to 8mg twice daily.
Where appropriate, the total daily dose may be converted to once daily administration using modified release formulations.
Galantamine should be taken after food to reduce the risk of cholinergic side effects (e.g. nausea, vomiting, diarrhoea). Administration with food slows rate of absorption but has no effect on total absorption. Modified release forms must be swallowed whole and not chewed.

Dose Modifications

Renal Impairment		**Hepatic Impairment**
eGFR >9ml/min	No dose adjustment	Max dose of 16mg in hepatic impairment Severe – avoid.
eGFR <9ml/min	Contra-indicated	

Contraindications

Known hypersensitivity to galantamine or any excipient.
Severe hepatic or renal impairment

Cautions

History of seizures
Pre-existing cardiac disease
Asthma or COPD
History of peptic ulcers or recovering from gastrointestinal surgery.
Urinary retention/bladder outflow obstruction

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What are the main side-effects?

The most common side-effects of cholinesterase inhibitors are nausea, mild anorexia, fatigue, diarrhoea, muscle cramps and sometimes poor sleep. Weight loss can also occur with donepezil. Patients should be advised to take the medicine with food to minimise side effects. Please refer to the BNF for further details. Serious skin reactions (Stevens-Johnson syndrome and acute generalized exanthematous pustulosis) have been reported in patients receiving galantamine. It is recommended that patients be informed about the signs of serious skin reactions, and that use of galantamine be discontinued at the first appearance of skin rash.

Drug Interactions

There are no specific dose changes which need to be made in relation to acetylcholinesterase inhibitors however it would be useful for prescribers to be aware of the following:

- Potent inhibitors of CYP3A4 (including ritonavir, clarithromycin and itraconazole) may raise galantamine levels.

The risk of adverse effects, including bradycardia, may be increased if an acetylcholinesterase inhibitor is given with amiodarone or other antihypertensive/antiarrhythmic drugs. Acetylcholinesterase inhibitors may antagonise effects of anticholinergic drugs and worsen Parkinsonian symptoms; this may induce or exacerbate extrapyramidal side effects.

Monitoring -

1. **Adverse effects:** Most common side effects are gastrointestinal disturbance (nausea, vomiting, and diarrhoea).
2. **Weight/BMI:** weight loss is associated with Alzheimer's disease but can also occur with acetylcholinesterase inhibitors.
3. **Concurrent medication:** Medication should be reviewed at each visit in order to identify potential drug interactions.
4. **Renal and hepatic function:** Baseline creatinine and LFTs should be measured; Patients with renal or hepatic impairment should have doses titrated slowly and be monitored closely for adverse effects.
5. **Cognitive, global functional and behavioural assessment:** Patients who continue on treatment should be reviewed at least annually by the GP. A cognition test may be done but, especially in more advanced dementia where benefits of cholinesterase inhibitors may cease to outweigh risks of continued treatment, an assessment of well-being and functioning is more important. Carers' views on the patient's condition at follow-up should be sought.

When should the drug be stopped?

Drugs should be stopped if a patient develops an allergy or contra-indication to the medication.
If treatment is considered to be no longer having a worthwhile effect on cognitive, global, functional or behavioural symptoms contact specialist for advice.
Where withdrawal of the treatment is advised this should be done gradually over a 4 week period.

When to seek Specialist advice / review

You can get advice regarding patients taking drug treatments for dementia from the locality memory treatment services in addition to CCG community pharmacy support.
Tolerability may change over time consequent upon the ageing process and the emergence of medical co-morbidities and frailty. In this situation it may appropriate to reduce the dose or discontinue treatment &/or consider an alternative drug. It may be appropriate to make such decisions in consultation with the specialist who initiated treatment.
You may wish to seek advice in the following circumstances:

- Emergent concerns regarding tolerability
- To consider whether to discontinue treatment at an advanced stage of the illness

Advice for patients having a general anaesthetic

Galantamine can enhance the effects of suxamethonium and the duration of the block may be prolonged.

Drug	Situation	Advice
Galantamine	Planned Operations	stop two days before surgery for washout
	Emergency operations	Inform the anaesthetist of potential of prolonged muscle relaxation.
	Post-operative	Re-introduce during post-surgical rehabilitation

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