Galzemic XL 8mg, 16mg, 24mg prolonged release Capsules (Galantamine) Prescribing Information. Prescribers should consult the SmPC before prescribing.

Presentation: Each Galzemic prolonged release capsule contains 8mg, 16mg, 24mg galantamine (as hydrobromide).

Indications: Symptomatic treatment of mild-moderately severe dementia of the Alzheimer type.

Dosage and administration: Adults/elderly: Confirm diagnosis of probable Alzheimer type dementia per current guidelines, prior to treatment. *Starting dose*: 8mg/day for 4 weeks. *Maintenance dose*: Increase dose to 16 mg/day, maintain for at least 4 weeks. Consider further increase to 24 mg/day following assessment of benefit and tolerability. Reassess tolerance and dosing within 3 months and regularly. Consider dose reduction to 16 mg/day if no increase in response or not tolerating. *Switching from immediate release tablets/oral solution*: administer same total daily dose. Take last dose of IR tablets in the evening, start Galzemic XL once daily the following morning. Concomitant treatment: Consider dose reduction in patients treated with potent CYP2D6 or CYP3A4 inhibitors.

Method of administration: Once daily administration in the morning, preferably with food. Capsules should be swallowed whole with liquid and must not be chewed or crushed. Adequate fluid intake during treatment should be ensured.

Special Populations: Renal impairment: No dose adjustment required when CrCl ≥9 ml/min. See contraindications. Hepatic impairment: Child-Pugh score 7-9: starting dose 8 mg once every other day, preferably in the morning, for 1 week, then 8 mg once daily for 4 weeks. Dose should not exceed 16 mg. See contraindications. Paediatric population: No relevant use.

Fertility, pregnancy and lactation: No clinical data available. Caution when prescribing to pregnant women. Women on galantamine must not breast-feed.

Contraindications: Hypersensitivity to active substance or excipients. Severe hepatic impairment (Child-Pugh score >9). Patients with CrCl <9 ml/min. Patients with both significant renal and hepatic dysfunction.

Special warnings and precautions: The benefit of galantamine is not demonstrated in other types of dementia or memory impairment. Alzheimer's dementia should be diagnosed by experienced physician. Treat with galantamine only under physician supervision. Initiate only if caregiver available to regularly monitor medicine intake. Serious skin reactions have been reported, inform patients of signs and discontinue use at first appearance of skin rash. Alzheimer's disease and galantamine treatment are associated with weight loss, monitor patient's weight. Galantamine may have vagotonic effects on heart rate, caution in patients with cardiovascular conditions or diseases. Monitor for symptoms in patients at increased risk of peptic ulcers. Not recommended in GI obstruction or patients recovering from GI surgery. Seizures have been reported. In rare cases an increase in cholinergic tone may worsen Parkinsonian symptoms. Cerebrovascular events reported uncommonly – consider in patients with cerebrovascular disease. Caution in patients with history of severe asthma or obstructive pulmonary disease or active pulmonary infection. Not recommended in patients with urinary outflow obstruction or recovering from bladder surgery. Likely to exaggerate succinylcholine-type muscle relaxation during anaesthesia, especially in pseudocholinesterase deficiency.

Drug Interactions: *Pharmacodynamic:* Do not give with other cholinomimetics (such as ambenonium, donepezil, neostigmine, pyridostigmine, rivastigmine or systematically administered pilocarpine). May antagonise effect of anticholinergic medication. Abrupt discontinuation of anticholinergic medication such as atropine may exacerbate the effect of galantamine. Possible interaction with medication that significantly reduce heart rate such as digoxin, beta-blockers, certain calcium-channel blocking agents and amiodarone. Caution with medicines that have potential to cause torsades de pointes – consider ECG. *Pharmacokinetic*: Potent inhibitors of CYP2D6 or CYP3A4 increase galantamine bioavailability and may increase incidence of cholinergic adverse reactions. Consider dose reduction in galantamine maintenance dose, based on tolerability.

Effects on ability to drive/use machines: minor or moderate influence. Possible dizziness and somnolence especially during first weeks of treatment.

Undesirable effects: Decreased appetite; hallucination; depression; hallucination visual; hallucination auditory; syncope; dizziness; tremor; headache; somnolence; lethargy; seizures; bradycardia; atrioventricular block complete, hypertension, hypotension; vomiting and nausea (mainly during titration period); abdominal pain; abdominal pain upper; diarrhoea; dyspepsia; abdominal discomfort, hepatitis, Stevens-Johnson Syndrome; acute generalised exanthematous pustulosis, erythema multiforme; muscle spasms; fatigue; asthenia; malaise, weight decreased, fall, laceration. See SmPC for full list of adverse events.

Pack sizes and UK list price: Galzemic XL 8mg prolonged-release capsules (PL 17780/0989) pack size: 28, £19.03, Galzemic XL 16mg prolonged-release capsules (PL 17780/0990) pack size: 28, £23.82, Galzemic XL 24mg prolonged-release capsules (PL 17780/0991) pack size: 28, £29.30.

Legal category: POM. **Marketing Authorisation Holder**: Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Zentiva via email to PV-United-Kingdom@zentiva.com or via phone on 0800 090 2408.