Luventa® XL Prescribing Information

Luventa® XL 8 mg, 16 mg and 24 mg prolonged-release capsules (galantamine) – Abridged Prescribing Information

Please consult the full Summaries of Product Characteristics (SmPC) for prescribing information.
Presentation: Prolonged release capsules containing 8 mg, 16 mg or 24 mg galantamine (as hydrobromide).
Indication: For the symptomatic treatment of mild to moderately severe Alzheimer type dementia.
Dosage and Administration: Patients must have a diagnosis of probable Alzheimer type dementia according to current clinical guidelines. Starting dose: 8 mg/day for 4 weeks. Maintenance dose: Tolerance and dosing should be reassessed regularly, within 3 months after start of treatment. Thereafter, the clinical benefit of galantamine and the patient's tolerance of treatment should be reassessed regularly according to current clinical guidelines. Continue maintenance treatment for as long as therapeutic benefit is favourable and the patient tolerates galantamine treatment. Consider discontinuing galantamine when evidence of therapeutic effect is no longer present or if patient does not tolerate treatment. Initial maintenance dose: 16 mg/day for at least 4 weeks. Consider increasing maintenance dose to 24 mg/day on an individual basis after assessment including evaluation of clinical benefit and tolerability. In patients who do not show an increased response or who do not tolerate 24 mg/day, consider decreasing dose to 16 mg/day. There is no rebound effect after abrupt discontinuation of treatment (e.g. in preparation for surgery). When switching to Luventa® XL prolonged release capsules from galantamine tablets or galantamine oral solution, it is recommended that the same total daily dose of galantamine is administered to patients. Patients switching to once daily regimen should take their last dose of galantamine tablets or oral solution in the evening and start Luventa® XL prolonged release capsules once daily the following morning. Special Populations: Hepatic and Renal impairment: Galantamine plasma levels may be increased in patients with moderate to severe hepatic or renal impairment. Patients with moderate hepatic impairment should begin dosing with Luventa® XL 8 mg prolonged release capsules every other day, preferably taken in the morning, for one week. Thereafter, patients should proceed with 8 mg once daily for 4 weeks. In such patients daily dosage should not exceed 16 mg. In patients with severe hepatic impairment galantamine use is contraindicated. No dose adjustment is required for patients with mild hepatic impairment. For patients with a creatinine clearance >9 ml/ml no dose adjustment is required. In patients with severe renal impairment (creatinine clearance <9 ml/ml) galantamine use is contraindicated. Concomitant treatment: In patients treated with potent CYP2D6 or CYP3A4 inhibitors dose reductions can be considered. Paediatric Population: There is no relevant use of galantamine in this population. Method of Administration: Administer once daily preferably in the morning with food. Swallow capsules whole with liquid. Do not chew or crush capsules. Switch patients to galantamine oral solution if they have difficulty swallowing. Ensure adequate fluid intake during treatment.
Contraindications: Hypersensitivity to the active substance or excipients. Severe or significant hepatic or renal impairment.
Warnings and Precautions: Treatment should occur under supervision of a physician and medicinal product intake should be monitored regularly. Cholinesterase inhibitor treatment (including galantamine) has been associated with weight loss - monitor patient's weight. Serious skin reactions: Stevens Johnson syndrome and acute generalised 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. Give with caution in the following conditions: Cardiac Disorders: Cholinomimetics may have vagotonic effects on heart rate e.g. bradycardia. This action may be important to patients with 'sick sinus syndrome', other supra-ventricular cardiac conduction disturbances, patients taking concomitant drugs that reduce heart rate e.g. digoxin, beta blockers or patients with uncorrected electrolyte disturbances e.g. hyperkalaemia and hypokalaemia. Exercise caution in patients with cardiovascular diseases e.g. immediate post-myocardial infarction period, new-onset atrial fibrillation, second degree heart block or greater, unstable angina pectoris and congestive heart failure especially NYHA group III – IV. An increased incidence of certain cardiovascular adverse events were observed in a pooled analysis of placebo controlled studies in patients with Alzheimer dementia treated with galantamine. Gastrointestinal Disorders: Patients at risk of peptic ulcer e.g. those with a history of, or predisposition to ulcer disease or those taking concomitant NSAIDs should be monitored for symptoms. Galantamine use is not recommended in patients with gastrointestinal obstruction or in those recovering from gastrointestinal surgery. Nervous system disorders: Cholinomimetics are believed to have some potential to cause seizures however, seizures may also be a manifestation of Alzheimer's disease. In rare cases, an increase in cholinergic tone may worsen Parkinsonian symptoms. Cerebrovascular events were uncommonly observed in Alzheimer's dementia patients treated with galantamine. Respiratory, Thoracic and Mediastinal Disorders: Prescribe with care in patients with severe asthma, obstructive pulmonary disease or active pulmonary infections (e.g. pneumonia). Renal and Urinary Disorders: Galantamine use is not recommended in patients with urinary outflow obstruction or in recovery from bladder surgery. Surgical and Medical Procedures: Galantamine may exaggerate succinylcholine-type muscle relaxation during anaesthesia especially in cases of pseudocholinesterase deficiency.
Interactions: Pharmacodynamic interactions: Do not give concomitantly with other cholinomimetics. Galantamine can antagonize the effect of anticholinergic medication. Should anticholinergics e.g. atropine, be stopped abruptly the effect of galantamine could be exacerbated. A pharmacodynamic interaction is possible with medicinal products that significantly reduce the heart rate e.g. digoxin, beta-blockers, certain calcium-channel blocking agents and amiodarone. Caution with medications that have the potential to cause torsades de pointes-consider an ECG in such cases. Galantamine, as a cholinomimetic, is likely to exaggerate succinylcholine-type muscle relaxation during anaesthesia, especially in cases of pseudocholinesterase deficiency. Pharmacokinetic interactions: The possibility of clinically relevant interactions is low. Concomitant administration with food slows the absorption rate of galantamine but does not affect the extent of absorption. It is recommended that galantamine be taken with food to minimise cholinergic side effects. Other medicinal products affecting the metabolism of galantamine: 40% increase in galantamine bioavailability with concomitant paroxetine (potent CYP2D6 inhibitor) therapy, 30% increase in galantamine bioavailability with concomitant ketoconazole (potent CYP3A4 inhibitor) therapy and 12% increase in galantamine bioavailability with concomitant erythromycin (potent CYP3A4 inhibitor) therapy. Therefore, patients may experience increased incidence of cholinergic adverse reactions, predominantly nausea and vomiting with potent inhibitors of CYP2D6 (e.g. quinidine, paroxetine or Fluoxetine) or CYP3A4 (e.g. ketoconazole or ritonavir). In these situations, consider reducing galantamine maintenance dose. Memantine, an N-methyl-D-aspartate (NMDA) receptor antagonist, at a dose of 10 mg once a day for 2 days followed by 10 mg twice a day for 12 days, had no effect on the pharmacokinetics of galantamine prolonged release capsules at steady state. Effect of galantamine on the metabolism of other medicinal products: Therapeutic doses of galantamine 24 mg/day had no effect on the kinetics of digoxin but pharmacodynamic interactions may occur. Therapeutic doses of galantamine 24 mg/day had no effect on the kinetics and prothrombin time of warfarin.
Fertility, Pregnancy and Lactation: Pregnancy: No data on exposed pregnancies is available. Reproductive toxicity has been shown in animal studies. Exercise caution in pregnant women. Breastfeeding: Unknown whether galantamine is excreted in human breast milk. No studies in lactating women. Women on galantamine should not breastfeed.
Driving: Caution is advised.
Undesirable Effects: Very common (≥1/10) – Nausea and vomiting. Common (≥1/100 to < 1/10) – Decreased appetite, anorexia, hallucinations, depression, syncope, dizziness, tremor, headache, somnolence, lethargy, bradycardia, hypertension, abdominal pain, upper abdominal pain, diarrhoea, dyspepsia, stomach discomfort, abdominal discomfort, hyperhidrosis, muscle spasms, fatigue, asthenia, malaise, decreased weight and falls. Uncommon (≥1/1000 to < 1/100) – Hypersensitivity, dehydration, visual hallucinations, auditory hallucinations, paraesthesia, dysgeusia, hypersomnia, seizures, blurred vision, tinnitus, supraventricular extrasystoles, first degree atrio-ventricular block, sinus bradycardia, palpitations, hypotension, flushing, retching, muscle weakness and increased hepatic enzymes. Rare (≥1/10,000 to <1/1000) – Hepatitis, Stevens-Johnson Syndrome: Acute Generalised exthematous Pustulosis; Erythema multiforme
Marketing Authorisation Numbers, Package Quantities and Basic NHS Price: Luventa® XL 8 mg – PL42924/0001; 28 capsule packs (£25.42). Luventa® XL 16 mg – PL 42924/0002; 28 capsule packs (£31.80). Luventa® XL 24 mg – PL42924/0003; 28 capsule packs (£39.10).
Legal Category: POM.
Marketing Authorisation Holder: Fontus Health Ltd.
60 Lichfield Street, Walsall. WS4 2BX.
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Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk. Adverse events should also be reported to Fontus Health Limited. Tel: 0121 661 4615.