Antial®

Galantamine

Description

Antial® is a preparation of Galantamine which is a cholinomimetic agent. It is a competitive and reversible inhibitor of the enzyme acetylcholinesterase. In addition, Galantamine enhances the intrinsic action of acetylcholine on nicotinic receptors. As a result, an increased activity in the cholinergic system associated with improved cognitive function can be achieved in patients with dementia of the Alzheimer's type.

Indication and usage

Antial® is indicated for the treatment of mild to moderate dementia of the Alzheimer's type.

Dose and administration

Adults:

The recommended starting dose of Antial® is 4 mg twice daily (8 mg/day). The dose should be increased to the initial maintenance dose of 8 mg twice daily (16 mg/day) after a minimum of 4 weeks. A further increase to 12 mg twice daily (24 mg/day) should be attempted after a minimum of 4 weeks at 8 mg twice daily (16 mg/day).

Antial® tablets should be administered twice daily, preferably with morning and evening meals.

Children

Galantamine is not recommended in children.

Hepatic impaired patients

In patients with moderately impaired hepatic function, the total daily dose should generally not exceed 16 mg/day. The use of Galantamine in patients with severe hepatic impairment is not recommended.

Renally impaired patients

For patients with moderate renal impairment the dose should generally not exceed 16 mg/day. In patients with severe renal impairment (creatinine clearance <9 mL/min), the use of Galantamine is not recommended.

Use in pregnancy and lactation

Galantamine is in pregnancy category B. Galantamine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It should not be used during breast-feeding. However, if its use is unavoidable, then breast-feeding should be discontinued.

Precautions

Caution should be taken in patients with cardiac disease; electrolyte disturbances; susceptibility to peptic ulcers; asthma, chronic obstructive pulmonary disease, pulmonary infection. Galantamine should be avoided in urinary retention and gastro-intestinal obstruction.

Side effects

Common side effects are nausea, vomiting, diarrhoea, abdominal pain, dyspepsia; syncope; rhinitis; sleep disturbances, dizziness, confusion, depression, headache, fatigue, anorexia, tremor; fever; weight loss; less commonly arrhythmias, palpitation, myocardial infarction, cerebrovascular disease, paraesthesia, tinnitus, and leg cramps.

Drug interactions
Galantamine should not be given concomitantly with other cholinomimetics and drugs that significantly reduce the heart rate (e.g., digoxin and beta blockers). It can also exaggerate succinylcholine-type muscle relaxation during anesthesia. During initiation of treatment with potent inhibitors of CYP2D6 (e.g., quinidine, paroxetine, fluoxetine or fluvoxamine) or CYP3A4 (e.g., ketoconazole), patients may experience an increased incidence of cholinergic side effects, predominantly nausea and vomiting.

Contraindications
Galantamine is contraindicated in patients with renal impairment; breast feeding and known hypersensitivity to the active substance or to any of the excipients.

Overdose
The symptoms of overdose usually involve areas like central nervous system, parasympathetic nervous system, and neuromuscular junction. Management of the overdose may require general supportive measures. In severe cases, anticholinergics, such as atropine, can be used as a general antidote for cholinomimetics. An initial dose of 0.5 to 1.0 mg intravenously is recommended, with subsequent doses based on the clinical response.

Pharmaceutical precautions
Store in a cool and dry place. Protect from light.

Presentation
Antial® 4 tablet: Each coated tablet contains Galantamine 4 mg as Hydrobromide USP
Antial® 8 tablet: Each coated tablet contains Galantamine 8 mg as Hydrobromide USP

Packaging
Antial® 4 tablet: Carton of 20 tablets in blister pack
Antial® 8 tablet: Carton of 10 tablets in blister pack

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ACI Limited