

Artigo®

Cinnarizine+Dimenhydrinate

Description

Artigo® is a combination of Cinnarizine and Dimenhydrinate. Cinnarizine acts predominantly on the peripheral vestibular system and acts mainly as a vestibular sedative through inhibition of the calcium influx into the vestibular sensory cells. On the other hand Dimenhydrinate acts predominantly on the central vestibular system. The substance exhibits anti-emetic and antivertiginous effects through influencing the chemoreceptor trigger zone in the region of the 4th ventricle.

Indication and usage

Artigo® is indicated for the treatment of vertigo symptoms of various origins.

Dose and administration

Adults:

1 Artigo® tablet three times daily after meals

Children and adolescents under the age of 18 years:

Not recommended

Elderly:

Dosage same as for adults

Patients with renal impairment:

Cinnarizine, Dimenhydrinate combination should be used with caution in patients with mild to moderate renal impairment. It should not be used by patients with a creatinine clearance of <25ml/min (severe renal impairment).

Patients with hepatic impairment:

No studies in patients with hepatic impairment are available. Cinnarizine, Dimenhydrinate combination should not be used by patients with severe hepatic impairment.

Use in pregnancy and lactation

The safety of Cinnarizine, Dimenhydrinate combination in pregnancy has not been established. Dimenhydrinate may have an oxytocic effect and may shorten labour. This combination should not be used during pregnancy. Dimenhydrinate and Cinnarizine are excreted in breast milk. Thus this combination should not be taken by lactating women.

Precautions

Cinnarizine, Dimenhydrinate combination may cause drowsiness, especially at the start of treatment. Patients affected in this way should not drive or operate machinery. This combination does not reduce blood pressure significantly; however, it should be used with caution in hypotensive patients. Cinnarizine, Dimenhydrinate combination should be used with caution in patients with conditions that might be aggravated by anticholinergic therapy, e.g. raised intra-ocular pressure, pyloro-duodenal obstruction, prostatic hypertrophy, hypertension, hyperthyroidism or severe coronary heart disease. Caution should be exercised when administering this combination to patients with Parkinson's disease.

Side effects

Common side-effects include somnolence and dry mouth. These reactions are usually mild and disappear within a few days even if treatment is continued. Following adverse reactions may also occur with Dimenhydrinate and Cinnarizine:

Dimenhydrinate: Paradoxical excitability (especially in children), worsening of an existing angle-closure glaucoma and reversible agranulocytosis.

Cinnarizine: Constipation, weight gain, chest tightness, cholestatic jaundice, extrapyramidal symptoms, lupus like skin reactions, lichen planus.

Drug interactions

The anticholinergic and sedative effects of Cinnarizine, Dimenhydrinate combination may be potentiated by monoamine oxidase inhibitors. In common with other antihistamines, Cinnarizine & Dimenhydrinate combination may potentiate the sedative effects of CNS depressants including alcohol, barbiturates, narcotic analgesics and tranquillizers. Patients should be advised to avoid alcoholic drinks. This combination may also enhance the effects of antihypertensives, ephedrine and anticholinergics such as atropine and tricyclic antidepressants.

Concomitant administration of medicines that prolong the QT interval of the ECG (such as Class Ia and Class III anti-arrhythmics) should be avoided.

Contraindications

Diphenhydramine is completely excreted renally, and Cinnarizine, Dimenhydrinate combination should not be used by patients with a creatinine clearance of ≤ 25 ml/min (severe renal impairment).

Since both Cinnarizine and Dimenhydrinate are extensively metabolized by hepatic cytochrome P450 enzymes, the plasma concentrations of the unchanged drugs and their half-lives will increase in patients with severe hepatic impairment. This should therefore not be used by patients with severe hepatic impairment.

Cinnarizine, Dimenhydrinate combination is contra-indicated in patients with known hypersensitivity to the active substances, diphenhydramine or other antihistamines of similar structure or to any of the excipients. This should not be used in patients with angle-closure glaucoma, convulsions, suspicion of raised intracranial pressure, alcohol abuse or urinary retention due to urethroprostatic disorders.

Overdose

Symptoms of overdosage with Cinnarizine, Dimenhydrinate combination include drowsiness, dizziness and ataxia with anticholinergic effects such as dry mouth, flushing of the face, dilated pupils, tachycardia, pyrexia, headache and urinary retention. Convulsions, hallucinations, excitement, respiratory depression, hypertension, tremor and coma may occur, particularly in cases of massive overdosage.

General supportive measures should be used to treat respiratory insufficiency or circulatory failure. Gastric lavage with isotonic sodium chloride solution is recommended. Cramp-like symptoms may be controlled by careful application of a short-acting barbiturate. In cases of marked central anticholinergic effects, physostigmine (after physostigmine test) should be administered slowly intravenously (or, if necessary, intramuscularly): 0.03 mg/kg body weight (adults max. 2 mg, children max. 0.5 mg). Sufficient elimination can be achieved by means of haemoperfusion using activated charcoal.

Pharmaceutical precautions

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

Presentation

Artigo[®] tablet : Each tablet contains Cinnarizine BP 20 mg & Dimenhydrinate USP 40 mg.

Package quantities

Artigo[®] tablet : Carton of 50 tablets in blister pack.

® Registered Trade Mark



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