

# Minium®

## Flunarizine

**Description:** Flunarizine (Minium®) is the difluorinated derivative of Cinnarizine.

**Mode of action:** Flunarizine is a selective calcium antagonist. It prevents cellular calcium overload by reducing excessive transmembrane influxes of calcium. It does not interfere with normal cellular calcium hemostasis. It has also antihistaminic properties. The effects of flunarizine in the prophylaxis of migraine are most pronounced with regards to the reduction of the frequency of attack.

**Pharmacokinetics:** Flunarizine is well absorbed from the gastrointestinal tract, peak plasma concentrations occurring 2 to 4 hours after oral administration. Flunarizine is very lipophilic and is more than 90% bound to plasma proteins. It appears to undergo extensive metabolism; metabolites are excreted principally in the bile. Flunarizine has an elimination half-life of about 18 days.

### Composition

**Minium® 5 mg Tablet:** Each tablet contains Flunarizine 5 mg as Flunarizine Dihydrochloride BP.

**Minium® 10 mg Tablet:** Each tablet contains Flunarizine 10 mg as Flunarizine Dihydrochloride BP.

**Indications:** Minium is indicated for

- Prophylaxis of classic (with aura) or common (without aura) migraine
- Symptomatic treatment of vestibular vertigo, dizziness
- Peripheral vascular disease (intermittent claudication, Raynaud's phenomenon, paresthesia, cold extremities, nocturnal cramp and trophic disorders owing to ischemia of limbs)
- Refractory epilepsy resistant to conventional antiepileptic therapy
- Alternating hemiplegia of childhood

**Dosage and administration:** *For migraine prophylaxis:* Starting dose is 10 mg daily (at night) for patients less than 65 years and 5 mg for patient older than 65 years.

*Maintenance treatment:* If a patient's response is satisfactory and if a maintenance treatment is needed, the dose should be decreased so that each week the patient has 5 days treatment at same daily dose and 2 successive drug free days. Treatment should be uninterrupted after 6 months and re-initiated only if the patient relapses. The recommended maximum daily dose is 10 mg daily in daily and 5 mg daily in children.

*For vertigo:* The recommended maximum daily dose of flunarizine in the treatment of vertigo is 10 mg daily in adults & 5 mg daily in children (<40kg).

*For epilepsy:* An optional therapeutic dosage in epileptic patients receiving other anti-epileptic drugs is 15 mg to 20 mg daily in adults and 5 to 10 mg daily in children.

**Contraindication:** Hypersensitivity to flunarizine or structurally similar calcium channel blocker, patients with a history of depressive illness, patients with pre-existing symptoms of Parkinson's disease or other extra pyramidal disorders, hepatic insufficiency (relatively contraindicated).

**Side effects:** Flunarizine is well tolerated and seldom causes serious side effects.

The main adverse effects experienced by the patients are as follows:

*Central nervous system:* Depression, drowsiness, sedation and anxiety.

*Gastrointestinal:* Heart burn, nausea, emesis, dry mouth, gastralgia.

*Miscellaneous:* Weight gain, increased appetite, asthenia, muscle aches, skin rash, and galactorrhea in female patients on oral contraceptives.

**Use in Pregnancy and Lactation:** *In pregnancy:* There is no data to support the use of flunarizine during pregnancy. Therefore it should not be administered to pregnant women unless the anticipated benefits outweigh the potential risks.

*In lactation:* Animal studies have shown that flunarizine is excreted in breast milk. Therefore breast-feeding should be discouraged in women taking flunarizine.

**Precautions:** Since sedation or drowsiness occur in some patients during treatment with flunarizine hydrochloride, patients should be cautioned against activities which require alertness or rapid, precise responses (e.g. operating machinery or a motor vehicle) until the response to the drug has been determined.

**Drug Interactions:** Galactorrhea has been reported in few women on oral contraceptives within first two months of flunarizine treatment. Hepatic enzyme inducers such as Carbamazepine and Phenytoin increase the metabolism of flunarizine and thus reduce its steady state level. So an increase in dose of the drug may be required. Concomitant use of a calcium channel blocker and amiodarone has been reported to result in sinus arrest and atrioventricular block. Excessive sedation can occur when alcohol, hypnotics or tranquilizers are taken simultaneously with flunarizine.

**Over dosage:** Acute over dosage has been reported and the observed symptoms were sedation, agitation and tachycardia. Treatment of acute overdosage consists of charcoal administration, induction of emesis or gastric lavage, and supportive measures. No specific antidote is known.

**Storage:** Store in a cool and dry place, away from light. Keep out of reach of children.

### Packaging

**Minium® 5 mg Tablet:** Each carton contains 10X5 tablets in blister pack.

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