

Flurizin[®]

Flunarizine Dihydrochloride BP

COMPOSITION

Flurizin[®] 5 : Each tablet contains Flunarizine 5 mg as Flunarizine dihydrochloride BP.

Flurizin[®] 10 : Each tablet contains Flunarizine 10 mg as Flunarizine dihydrochloride BP.

PHARMACOLOGY

Flurizin[®] (Flunarizine) is the difluorinated derivative of cinnarizine. It is a selective calcium channel antagonist. By reducing excessive transmembrane influx of calcium **Flurizin[®]** prevents cellular calcium overload. It does not interfere with normal cellular calcium homeostasis. **Flurizin[®]** also has some antihistaminic and sedative properties. It binds at an affinity of 99% to plasma protein.

INDICATION

Flurizin[®] is indicated for

- Prophylaxis of classic (with aura) or common (without aura) migraine
- Symptomatic treatment of vestibular vertigo (due to a diagnosed functional disorder of the vestibular system).
- Peripheral Vascular Disease (PVD)
- Motion sickness
- Refractory epilepsy resistant to conventional antiepileptic therapy.

DOSAGE & ADMINISTRATION

Migraine Prophylaxis:

Starting Dose: 10 mg at night in patients less than 65 years of age and 5 mg daily in patients older than 65 years. If, during this treatment depressive, extrapyramidal or other unacceptable symptoms occur, administration should be discontinued. If, after 2 months of this initial treatment, no significant improvement is observed, the patient should be considered a non-responder and administration should be discontinued.

Maintenance Treatment: If a patient is responding satisfactorily and if a maintenance treatment is needed, the dose should be decreased to 5 days treatment at the same daily dose with two successive medicine free days every week. Even if the prophylactic maintenance treatment is successful and well tolerated, it should be interrupted after 6 months and it should be re-initiated only if the patient relapses.

Peripheral Vascular disease: 10 mg twice daily, up to 30 mg per day if required.

Vertigo & motion sickness: 10-20 mg daily for adults and 5 mg daily for children (> 40 kg).

Epileptic seizure: 15-20 mg daily in adults and 5 to 10 mg daily for children as an add-on therapy.

CONTRAINDICATION

Hypersensitivity to Flunarizine. Flunarizine is contra-indicated in patients with a history of depressive illness, or with pre-existing symptoms of Parkinson's disease or other extrapyramidal disorders.

WARNINGS & PRECAUTION

Flunarizine may lead to drowsiness which is aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be cautioned against driving motor vehicles or performing other potentially hazardous tasks where a loss of mental alertness may lead to accidents. Flunarizine is not suited for aborting a migraine attack. The possible occurrence of an attack is therefore no reason to increase the dose of Flunarizine. This treatment may give rise to extrapyramidal and depressive symptoms and reveal Parkinsonism, especially in predisposed patients such as the elderly. Flunarizine should therefore be used with caution in such patients.

SIDE EFFECTS

Drowsiness and/or fatigue, as well as weight gain and/or increased appetite may occur. The following adverse experiences have been reported during chronic treatment with Flunarizine: depression, of which female patients with a history of depressive illness may be particularly at risk; extrapyramidal symptoms (such as bradykinesia, rigidity, akathisia, orofacial dyskinesia, tremor), of which elderly patients seem particularly at risk. Infrequently reported adverse reaction are: heartburn; nausea; gastralgia; insomnia; anxiety; galactorrhoea; dry mouth; muscle ache; skin rash.

DRUG INTERACTIONS

Galactorrhoea has been reported in few women on oral contraceptives within the first two months of Flunarizine treatment. Hepatic enzyme inducers such as Carbamazepine and Phenytoin may interact with flunarizine by increasing its metabolism. So an increase in dosage of flunarizine may be required.

USE IN PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

STORAGE

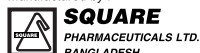
Store at a cool & dry place, protected from light and moisture. Keep out of reach of the children.

HOW SUPPLIED

Flurizin[®] 5 tablet: Each box contains 50 tablets in blister packs.

Flurizin[®] 10 tablet: Each box contains 50 tablets in blister packs.

Manufactured by :



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