

# Flurium®

Flunarizine

Tablet

## Description

Flunarizine is the difluorinated derivative of Cinnarizine. Flunarizine is a selective calcium channel 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 and sedative properties.

## Indications

- 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 patients 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 the same daily dose and 2 successive drug free days. Treatment should be interrupted after 6 months and re-initiated only if the patient relapses. The recommended maximum daily dose is 10 mg daily in adults 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 optimal 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.

## 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, and/or increased appetite, asthenia, muscle aches, skin rash, and galactorrhoea in female patients on oral contraceptives.

## Contraindications

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).

## 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.

## 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.

## Overdose

Acute overdosage 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.

## Drug Interactions

Galactorrhoea 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.

## Pharmaceuticals Precautions

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

## Commercial Pack

Flurium®5 Tablet: Each box contains 3 blister strips of 10 tablets. Each tablet contains Flunarizine Dihydrochloride BP equivalent to Flunarizine 5 mg.

Flurium®10 Tablet: Each box contains 3 blister strips of 10 tablets. Each tablet contains Flunarizine Dihydrochloride BP equivalent to Flunarizine 10 mg.



Manufactured by

**BEXIMCO PHARMACEUTICALS LTD.**

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