Norium®

Flunarizine Tablet BP

DESCRIPTION

Norium® is the preparation of flunarizine dihydrochloride. 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 homeostasis. 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, paresthesiae, cold extremities, nocturnal cramp and trophic disorders owing to ischaemia 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 daily 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 (<40 kg).

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

USE IN THE ELDERLY

The efficacy of flunarizine in the prophylaxis of migraine has not been established in elderly subjects. Moreover, treatment with flunarizine may give rise to extrapyramidal and depressive symptoms and reveal parkinsonism, especially in the elderly. Therefore, it should be used with caution.

USE IN PATIENTS WITH IMPAIRED HEPATIC FUNCTION

Flunarizine is metabolised by the liver, therefore care should be exercised when flunarizine is given to patients with compromised liver function.

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.

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, anxiety
Gastrointestinal : Heart burn, nausea, emesis, dry mouth, gastralgia
Miscellaneous : Weight gain,and/or increased appetite, asthenia, muscle aches, skinrash, and galactorrhea 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)

DRUG INTERACTIONS

Galactorrhea 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 increase the metabolism of flunarizine and thus reduce it's steady state level. So an increase in dose of the drug may be required. Concomitant use of a calcium channel blocker and amiodorone 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.

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.

SYMPTOMS AND TREATMENT OF OVERDOSE

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

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Norium® 5 mg tablet : Box containing 10 strips of 10 tablets each. Each tablet contains Flunarizine Dihydrochloride BP equivalent to Flunarizine 5 mg.

Norium® 10 mg tablet : Box containing 6 strips of 10 tablets each. Each tablet contains Flunarizine Dihydrochloride BP equivalent to Flunarizine 10 mg.

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TONGI, GAZIPUR, BANGLADESH

PM04256 V02