Abridged Prescribing Information:

Active Ingredient MIGRANEX tablet contains Flunarizine Dihydrochloride 5mg/10mg

Indication: For migraine- As a maintenanace treatment for classical and common migraine (prophylaxis).

Dosage & Administration: **(i) Migraine: Starting dose Adults (<65 years):** Two 5 mg tablets (i.e., 10 mg) daily to be taken at night. Elderly (<65 years): One 5 mg tablet daily to be taken at night. Note: If during this treatment depressive, extrapyramidal, or other unacceptable adverse experiences occur, discontinue the drug. Also, if no significant improvement is seen after 2 months of initial therapy, discontinue the drug. **Migraine: Maintenance dose:** Given to patients who have responded to initial therapy satisfactorily and who need maintenance therapy. Dose is decreased (usually to 5 mg daily). This dose is given daily every 5 days and no drug for the remaining 2 successive days in a week. Therapy is discontinued after 6 months and reinitiated only when there is a relapse of migraine. **Contraindication:** Known hypersensitivity to flunarizine or to other ingredients of the product, Patients with a history of depressive illness, Patients with pre-existing symptoms of Parkinson's disease **Warnings & Precautions: Extrapyramidal Symptoms**: Clinical studies indicate that flunarizine treatment, even at recommended doses, can produce motor disturbances in subjects who did not show previous neurological deficits. Elderly patients appear to be particularly at risk. The clinical symptoms resemble Parkinson's disease, however, they do not improve with antiparkinson medication. Experience to date suggests that in most instances the extrapyramidal symptoms tend to be reversible following discontinuation of flunarizine treatment. **Depression:** Clinical studies indicate that flunarizine can, even at recommended doses, precipitate depression, mostly in younger patients. **Fatigue**: In rare cases fatigue may increase progressively during flunarizine therapy. In this event, therapy should be discontinued. **Pregnancy:** To date, there are no data to support the use of flunarizine during pregnancy. It should therefore not be administered to pregnant women unless the anticipated benefits outweigh the potential risks. **Special Population**: **Endocrine Effects:** Galactorrhea has been reported in a few female patients, some of whom were also on oral contraceptives, within the first two months of flunarizine treatment. Discontinuation of flunarizine therapy resolved the galactorrhea in most cases. Flunarizine therapy caused a mild but significant elevation of serum prolactin levels while GH, LH, FSH, and TSH levels did not show significant variation. A few cases of menstrual irregularities have been reported. **Use in Patients with Impaired Hepatic Function:** Flunarizine is extensively metabolized by the liver; therefore, care should be exercised when flunarizine is given to patients with compromised liver function. **Adverse Reactions:** The most frequent adverse experiences are drowsiness, and/or fatigue (20%), which are generally transient, and also weight gain (and/or increased appetite) (11%). The following serious adverse experiences may occur during chronic treatment: 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 **Overdose:** On the basis of the pharmacological properties of the drug, sedation and asthenia may be expected to occur. A few cases of acute overdosage (up to 600 mg in one intake) have been reported and the observed symptoms were sedation, agitation, and tachycardia. There is no specific antidote. Treatment of acute overdosage consists of charcoal administration, induction of emesis or gastric lavage, and supportive measures. Within the first hour after ingestion, gastric lavage may be performed. Activated charcoal may be given if considered appropriate.

(For details, please refer full prescribing information)

Version date: 03/03/2023. If you require any further information, please reply us on

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