Abridged prescribing information
Sabril tablets / sachets.

Indications

Treatment of refractory epilepsy, particularly partial epilepsy in adults and children, excluding petit mal, in addition to existing treatment.

Dosage and administration

Adults: Recommended starting dose: 2 grams (4 tablets) in one or two daily doses in addition to existing treatment. If necessary increased or decreased in 0.5g or 1g increments depending on clinical response and tolerability. An increase in the daily dose above 4g does not usually improve efficacy.

Children: treatment should be started with a dose of 40mg/kg which can be increased gradually to 80-100mg/kg.

In infants with West's syndrome doses of 100mg/kg per day may be necessary.

Elderly and patients with renal impairment: Consider dose reduction particularly if creatinine clearance is less than 60ml/min. Start treatment with the lowest dose and monitor closely for adverse events in particular sedation and signs of confusion.

Contraindications Hypersensitivity to vigabatrin or any of the components.

Precautions: In view of the frequency of psychiatric adverse effects, treatment with vigabatrin should not be considered in patients with a history of psychiatric disease unless the use of this product is considered to be an absolute necessity. Careful monitoring of these patients is mandatory. As with all antiepileptics, abrupt withdrawal of treatment may lead to rebound seizures; therefore in case of withdrawal from treatment with Sabril, it is recommended a gradual dose reduction.

Pregnancy: In absence of clinical data the product should not be used in pregnant women.

Lactation: Breast feeding is not recommended during treatment with Sabril.

Warnings: Animal safety studies indicate that vigabatrin causes intramyelinic oedema in the brain of some species. There is no evidence that this effect occurs in man. However, it is recommended that patients treated with vigabatrin are closely observed for adverse effects on neurological function.

Effects on driving ability: Drowsiness has been observed and patients should be warned.

Side-effects: Are mainly CNS related. The most common are drowsiness and fatigue; other effects have been reported in particular vertigo, agitation, irritability, depression, headache and, less often, psychosis, confusion, memory loss and diplopia. Also weight gain, minor gastro-intestinal disturbances and decrease in SGOT and SGPT have been observed.

In children the most frequent adverse reactions are: agitation, excitation, and occasionally insomnia. These reactions occur at the start of treatment and disappear gradually if they are followed by a reduction in dosage.

Drug interactions: Are unlikely. A gradual reduction of up to a maximum of 20% in plasma phenytoin concentration has been observed. No clinically significant interactions with carbamazepine, phenobarbital or sodium valproate.

Presentation: ~~100 tablets, each containing 500mg vigabatrin, in theamp-formed strips.~~
~~Full prescribing information available with: Marion Merrell Dow MidEast/Afric., Via R. Lepetit 8, 20020 Lainate, Italy.~~

References

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