INDIA

TAJ PHARMACEUTICALS LIMITED

CNS | TAJ

Introducing new 5 products
for Central Nervous System (CNS) disorders .
Products for Central Nervous System Disorders

Vegarin

Tablets and Oral Solution

Rx only

Vegarin Tablets
Vegarin for Oral Solution

Indication
Vegarin is indicated as adjunctive therapy for adult patients with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Vegarin is not indicated as a first line agent for complex partial seizures.
Vegarin is indicated as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms (IS) for whom the potential benefits outweigh the potential risk of vision loss.

Important Safety Information

WARNING: VISION LOSS
See full Prescribing Information for complete boxed warning

• Vegarin causes progressive and permanent bilateral concentric visual field constriction in a high percentage of patients. In some cases, Vegarin may also reduce
visual acuity.

• Risk increases with total dose and duration of use, but no exposure to Vegarin is known that is free of risk of vision loss

• Risk of new and worsening vision loss continues as long as Vegarin is used, and possibly after discontinuing Vegarin

• Periodic vision testing is required for patients on Vegarin, but cannot reliably prevent vision damage

• Because of the risk of permanent vision loss, Vegarin is available only through a special restricted distribution program

VEGARIN causes permanent vision loss in infants, children, and adults. Because assessing vision loss is difficult in children, the frequency and extent of vision loss in infants and children is poorly characterized.
In adults, VEGARIN causes progressive and permanent bilateral concentric visual field constriction in 30% or more of patients that ranges in severity from mild to severe, including tunnel vision to within 10° of visual fixation, and can result in disability. In some cases, VEGARIN also can damage the central retina and may decrease visual acuity. The lowest dose and shortest exposure to VEGARIN should
be used that is consistent with clinical objectives.

Because of the risk of permanent vision loss, VEGARIN should be withdrawn from a pediatric patient treated for IS (1 month to 2 years of age) who fails to show substantial clinical benefit within 2 to 4 weeks of treatment initiation, or sooner ifactivity rather than to abolish the primary focus of seizure discharges.

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In adults, VEGARIN causes progressive and permanent bilateral concentric visual field constriction in 30% or more of patients that ranges in severity from mild to severe, including tunnel vision to within 10° of visual fixation, and can result in disability. In some cases, VEGARIN also can damage the central retina and may decrease visual acuity. The lowest dose and shortest exposure to VEGARIN should be used that is consistent with clinical objectives.

Because of the risk of permanent vision loss, VEGARIN should be withdrawn from a pediatric patient treated for IS (1 month to 2 years of age) who fails to show substantial clinical benefit within 2 to 4 weeks of treatment initiation, or sooner if treatment failure becomes obvious, or an adult patient treated for refractory CPS as adjunctive therapy who fails to show substantial clinical benefit within 3 months of treatment initiation, or sooner if treatment failure becomes obvious.

Vision testing for adults treated for refractory CPS as adjunctive therapy is required at baseline (no later than 4 weeks after starting VEGARIN) and at least every 3 months while on therapy. Vision testing for pediatric patients treated for IS is required to the extent possible at baseline (no later than 4 weeks after starting VEGARIN) and at least every 3 months while on therapy. Once detected, vision loss is not reversible. It is expected that, even with frequent monitoring, some patients will develop severe vision loss. Vision testing for adults and pediatric patients is also required about 3 to 6 months after discontinuing VEGARIN therapy. The onset of vision loss from VEGARIN is unpredictable and can occur within weeks of starting treatment or sooner, or at any time during treatment, even after months or years. Patient response to and continued need for VEGARIN should be periodically reassessed.

Symptoms of vision loss from VEGARIN are unlikely to be recognized by the patient, parent or caregiver before vision loss is severe. Vision loss of milder severity, although unrecognized by the patient, parent or caregiver may still adversely affect function. The possibility that vision loss from VEGARIN may be more common or more severe, or have more severe functional consequences in infants and children than in adults, cannot be excluded.

VEGARIN should not be used in patients with, or at high risk of, other types of irreversible vision loss or with other drugs associated with serious adverse ophthalmic effects such as retinopathy or glaucoma unless the benefits clearly outweigh the risks. The interaction of other types of irreversible vision damage with vision damage from VEGARIN has not been well characterized, but is likely adverse.

In adult patients treated for CPS, dose adjustment, including initiating treatment with a lower dose, is necessary in patients with renal impairment. A 16% to 20% average reduction in total phenytoin plasma levels was reported in controlled clinical studies.

Abnormal MRI signal changes have been observed in some infants treated for IS with VEGARIN. These changes generally resolved with discontinuation of treatment and in a few patients the lesion resolved despite continued use.

VEGARIN should be discontinued gradually to avoid withdrawal seizures. In controlled clinical studies in adults with CPS, VEGARIN was tapered by decreasing the daily dose at a rate of 1 g/day on a weekly basis until discontinued. In a controlled clinical study in patients with IS, vigabatrin was tapered by decreasing the daily dose at a rate of 25 to 50 mg/kg every 3 to 4 days.

Antiepileptic drugs (AEDs), including VEGARIN, increase the risk of suicidal thoughts or behavior. Adult patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior and/or any unusual changes in mood or behavior.

VEGARIN has been shown to cause neurotoxicity, anemia, somnolence, fatigue, weight gain, edema, and symptoms of peripheral neuropathy. VEGARIN should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Vigabatrin is excreted in human milk and may cause serious adverse events in nursing infants.

The most commonly observed adverse reactions reported in 2 add-on clinical studies of adults with refractory CPS treated with VEGARIN as adjunctive therapy with the recommended dose of 3 g/day (≥10% and at least 5% greater than placebo) were dizziness (VEGARIN 24% vs placebo 17%), fatigue (VEGARIN 23% vs placebo 16%), somnolence (VEGARIN 22% vs placebo 13%), tremor (VEGARIN 15% vs placebo 8%), blurred vision (VEGARIN 13% vs placebo 5%), and arthralgia (VEGARIN 10% vs placebo 3%). A 6 g/day dose has not been shown to confer additional benefit compared to the 3 g/day dose and is associated with an increased incidence of adverse events.

The most common adverse events reported by >5% of infants taking VEGARIN for IS occurring more frequently than placebo in a randomized, placebo-controlled IS study with a 5-day double-blind treatment phase (n=40) were somnolence (VEGARIN 45% vs placebo 30%), bronchitis (VEGARIN 30% vs placebo 15%), ear infection (VEGARIN 10% vs placebo 5%), and acute otitis media (VEGARIN 10% vs placebo 0%).

Pregnancy Registry: To provide information regarding the effects of in utero exposure to VEGARIN, physicians are advised to recommend that pregnant patients taking VEGARIN enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. This can be done by calling the toll-free number 1-888-233-2334, and must be done by patients themselves. Information on the registry can also be found at the website http://www.aedpregnancyregistry.org/.

Oral Solution: For more information, please see the full Prescribing Information including Boxed Warning, Medication Guide and Dosing Instructions.

Solución oral: Para más información, vea por favor la información que prescribe completa incluyendo la advertencia encajonada, guía de la medicación y las instrucciones de la dosificación.

Tablets: For more information, please see the full Prescribing Information including Boxed Warning and Medication Guide.

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