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SABRIL REMS Program Fact Sheet for Eye Care Professionals[1]

Risk of Permanent Vision Loss

- SABRIL® (vigabatrin) can cause permanent, bilateral, concentric visual field constriction, including tunnel vision that can result in disability. In some cases, SABRIL may also decrease visual acuity.
- Risk increases with increasing dose and cumulative exposure, but there is no dose or exposure to SABRIL known to be free of risk of vision loss.
- Risk of new and worsening vision loss continues as long as SABRIL is used, and possibly after discontinuing SABRIL.
- Baseline and periodic vision assessment is recommended for patients on SABRIL. However, this assessment cannot always prevent vision damage.

Monitoring of Vision

- Periodic monitoring of vision by an ophthalmic professional with expertise in visual field interpretation and the ability to perform dilated indirect ophthalmoscopy of the retina is recommended.
- The diagnostic approach should be individualized for the patient and clinical situation.
- In adults and cooperative pediatric patients, perimetry is recommended, preferably by automated threshold visual field testing.
- Additional testing may also include electrophysiology (e.g., electroretinography [ERG]), retinal imaging (e.g., optical coherence tomography [OCT]), and/or other methods appropriate for the patient.

Recommended Vision Testing Schedule

Baseline	Vision assessment is recommended at baseline (no later than 4 weeks after starting SABRIL).
Ongoing Monitoring	Vision assessment is also recommended every 3 months while the patient continues on SABRIL.
After Discontinuation	Vision assessment is also recommended 3-6 months after the patient discontinues SABRIL.

Abnormal Vision Test Results

- Because of variability, results from ophthalmic monitoring must be interpreted with caution, and repeat assessment is recommended if results are abnormal or uninterpretable.
- The onset and progression of vision loss from SABRIL is unpredictable, and it may occur or worsen precipitously between assessments.
- Once detected, vision loss due to SABRIL is not reversible. It is expected that even with frequent monitoring, some SABRIL patients will develop severe vision loss.
- Consider drug discontinuation, balancing benefit and risk, if vision loss is documented. It is possible that vision loss can worsen despite discontinuation of SABRIL.

For more information, please see the accompanying Prescribing Information and Medication Guide.

References:

1. SABRIL [package insert]. Deerfield, IL: Lundbeck.

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