

FDA Public Meeting October 5-6, 2015

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IS, Sabril, and REMS

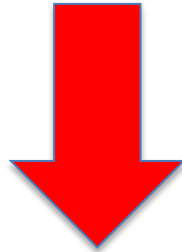
- Severe form of epilepsy with poor long-term developmental outcomes, especially if not controlled quickly.
- Often hundreds of seizures/day
- Vigabatrin (Sabril)
 - one of only two first-line drugs for IS
 - Potential vision complications → REMS
 - Vision testing required at baseline and every 3 months
 - Prescribed during acute illness
 - Overwhelmingly stressful time for families

ISC

- Founded in 2006
- 3,000+ members
- 100's of forum posts daily
 - Sabril REMS frequent topic
- Families polled for this presentation

Burden on Providers

- Documentation, consent process
- Confusion surrounding vision testing requirements
- Lack of access to ophthalmology resources
- Stigma of the REMS, perception of drug risks, liability



- **Some centers do not prescribe this first-line drug**
 - “Let someone else handle it.”
 - Offer second-line medication
 - Refer families to other centers often 100’s of miles away

“Our neurologist won't/can't prescribe Sabril and said if we wanted to go that route we would have to head to Seattle. Instead we put our [child] on [a second-line drug].”

-- ISC Community mother

“Our first neurologist would not prescribe Sabril to us. We had to drive 500 miles to another state to get Sabril. Spasms stopped after second dose.”

-- ISC Community mother

Burden on Patients and Caregivers

- Paperwork, calls
- Cannot get drug at hospital
- Stressful wait to begin medication
 - Must be home to sign for package
- Run out of drug
 - Specialty pharmacy
 - Last minute refills
 - Holiday/weekend/other delivery issues
- Inconsistent application of vision exam:
- ERG (sedation/anesthesia or physical restraint) vs. traditional eye exam
- Requests for redundant documentation

“[The] only issue I've encountered is getting my son's eye exams reported back to SHARE. When he had his first eye exam, we were referred to a specialist at a different hospital. When I took him for his exam (exact same exam that he had the first time), he was actually past his three month requirement because we had to wait to get in. After his eye exam, they failed to return the paperwork. When they did, they failed to have it signed by his neurologist. It was pretty frustrating.”

--ISC mom

Recommendations

- Allow hospitals to keep drug on hand
- Repository for extra meds
- Guidelines/clarification/best practices for vision testing
 - Populations best suited for various testing modalities
 - Exemptions
- Streamline vision test documentation reporting
- Satisfaction survey of providers and patients

Thank you!

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