ANALYSIS OF CUTANEOUS ALLERGIC REACTIONS IN CLINICAL TRIALS OF ESL

Rogin J, et al. *Acta Neurol Scand* 2020;141:397–404

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OBJECTIVE

Evaluate cutaneous allergic reactions in randomized, double-blind, placebo-controlled studies of adjunctive ESL for focal seizures in children and adults

STUDY DESIGN

Adult studies

Pooled data from Phase III clinical trials

Patients aged ≥16 years with focal seizures not adequately controlled with 1–3 ASMs

BIA-2093-301
BIA-2093-302
BIA-2093-304

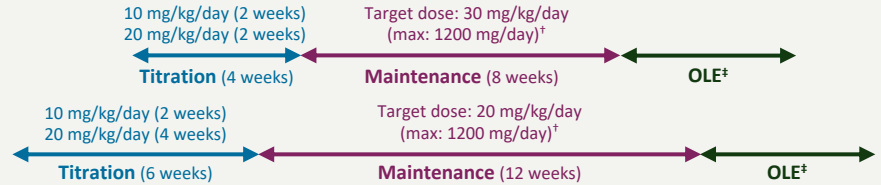
Pediatric studies

Pooled data from Phase II/III clinical trials with OLEs

Patients aged 4–17 years with focal seizures

BIA-2093-208
Phase II

BIA-2093-305
Phase III



*Studies 301 and 302 only. †Dose reduction was allowed once, during either the titration period (from 20 to 10 mg/kg/day) or the maintenance period (from 30 to 20 mg/kg/day or 20 to 10 mg/kg/day). ‡Patients who chose not to enter the OLE entered a 4–8-week taper/follow-up period.

RESULTS

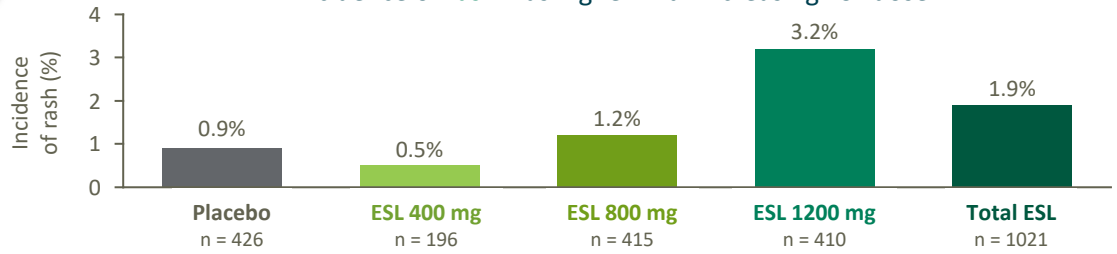
ADULT

The **most common rash-related TEAEs** were:

- **Rash** 0.9% vs **1.9%**
- **Pruritus** 0.9% vs **1.2%**
- **Contact dermatitis** 0.2% vs **0.3%**
- **Eye pruritus** 0 vs **0.3%**

Placebo n = 426
ESL n = 1021

Incidence of rash was higher with increasing ESL dose[1]



PEDIATRIC

The **most common rash-related TEAEs** were:

In the **controlled study period** Placebo: n = 160 | ESL: n = 202

- **Allergic dermatitis** 0 vs **3.0%**
- **Rash** 1.3% vs **1.0%**
- **DRESS** 0 vs **0.5%**
- **Pruritus** 0 vs **0.5%**

In the **1-year OLE with ESL** n = 337

- **Rash 1.2%**
- **Urticaria 0.6%**
- **Vesicular rash 0.3%**
- **Allergic dermatitis 0.3%**
- **Hypersensitivity 0.3%**

In the **post-1-year OLE with ESL** n = 177

- **Rash 0.6%**

DRESS: A severe adverse drug reaction characterized by an extensive skin rash in association with visceral organ involvement, lymphadenopathy, eosinophilia, and atypical lymphocytosis, with a long latency period

36-year-old female (Study 301)
Potential DRESS
- ESL 1200 mg
- Hospitalized & AE classified as serious
- Recovered 5 days after discontinuing ESL

44-year-old female (Study 301)
Potential DRESS
- ESL 400 mg
- Not hospitalized & AE not classified as serious
- Did not discontinue ESL

5-year-old female (Study 305)
DRESS
- ESL 200 mg
- Hospitalized & AE classified as serious
- Recovered 32 days after discontinuing ESL

CONCLUSIONS

AEs characterized as serious skin rashes were rare during adult and pediatric clinical trials of ESL; however, it is important for patients/caregivers to be aware of the potential signs and symptoms associated with serious skin rashes

Disclaimer: Serious dermatologic reactions including Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in association with use of ESL and/or oxcarbazepine or carbamazepine (chemically related to ESL)

Abbreviations: AE, adverse event; ASM, antiseizure medication; DRESS, drug reaction with eosinophilia and systemic symptoms; ESL, eslicarbazepine acetate; OLE, open-label extension; QD, once daily; TEAE, treatment-emergent adverse event. [1]Reprinted from Rogin J, et al. Analysis of cutaneous allergic reactions in clinical trials of eslicarbazepine acetate. Acta Neurol Scand 2020;141:397– 404. https://onlinelibrary.wiley.com/doi/abs/10.1111/ane.13218.

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