Six-month levetiracetam treatment in epileptic patients after branded-to-generic switch; a community-based retrospective study

1)Rigamonti AE.

DISCO, University of Milan

INSERIRE GRAFICO. Patients and clinicians share concerns that branded-to-generic antiepileptic drug substitution might lead to loss of seizure control or occurrence of adverse events. Few clinical studies have reported conflicting results after switch of branded-to-generic levetiracetam (LEV).

Aim of the present study was that of assessing the 6-month efficacy and tolerability of LEV after branded-to-generic switch in real-world clinical practice. In particular, we retrospectively analyzed 178 epileptic patients attending community-based neurology clinics who were treated with branded LEV for at least 6 months and then switched to generic LEV, with a final clinical evaluation after 6 other months. The primary endpoints were: 6-month retention rate, reasons for discontinuation and percentage of seizure-free patients.

The retention rate at 6 months after branded-to-generic switch was 98,31% (vs. 100% at the end of branded LEV treatment). In 2 of the 178 patients (1,12%), the treatment with generic LEV was discontinued due to lack of efficacy, the same reason for which branded LEV was replaced with the generic version. In 1 patient (0,56%), treatment with generic LEV was discontinued due to the occurrence of an adverse event (worsening of somnolence). In total, 80 of the 178 patients (45%) were seizure-free after 6 months of generic LEV (vs. 42% at the end of branded LEV treatment).

In conclusions, in a real-world setting, generic LEV is an effective and well-tolerated product 6 months after switch from the corresponding branded version.

Seizure frequency (all seizure types) per month and -50% responder rate before and during branded and generic LEV treatments (completers)

	Before LEV	After branded LEV	After generic LEV
Range of seizure frequency (per month)	3-5	0-5	0-5
Responder rate (-50%)	NA	86.5%	90.4%
Seizure frequency per month	6.0±7.1	1.4±2.1*	1.2±1.8*

*p<0.05 vs. before LEV