JOSEIZ™

Lacosamide Tablets 50 mg / 100 mg

Description:

JOSIEZ contains lacosamide tablets in the strength of 50 mg and 100 mg. Lacosamide is a functionalized amino acid that has activity in the maximal electroshock seizure test, and is indicated for the adjunctive treatment of partial-onset seizures.

Mechanism of Action:

The precise mechanism by which lacosamide exerts its antiepileptic effect in humans is unknown. In vitro electrophysiological studies have shown that lacosamide selectively enhances slow inactivation of voltage-gated sodium channels, resulting in reduced hyper excitability of neuronal membranes and inhibition of repetitive neuronal firing.

Indication:

Lacosamide is indicated as adjunctive therapy in the management of partial-onset seizures in adult patients with epilepsy.

Dosage:

Film-coated tablets

On the first day of treatment the patient starts with lacosamide 50 mg tablets twice a day. During the second week, dose of lacosamide can be increased to 100 mg tablets twice a day. Depending on response and tolerability.

Administration:

It comes as Film Coated tablets and to be taken by mouth with or without food.

Storage:

Store at a temperature not exceeding 30°C, protected from light and moisture.

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Background:

The term ***epilepsy*** refers to a number of different syndromes characterized by spontaneous or unprovoked disturbances in brain activity with varying characteristics, duration, and severity.[1]

Lacosamide was approved in August 2008 by the European Commission & in October 2008 by the Food & Drug Administration as an adjunctive therapy for partial onset seizures in patients with epilepsy aged 16 & older (Europe) / 17 and older (United States).[2]

Reference: 1. Annals of the New York Academy of Sciences,2013 | 2. British Epilepsy Association,2012

Clinical Effectiveness:

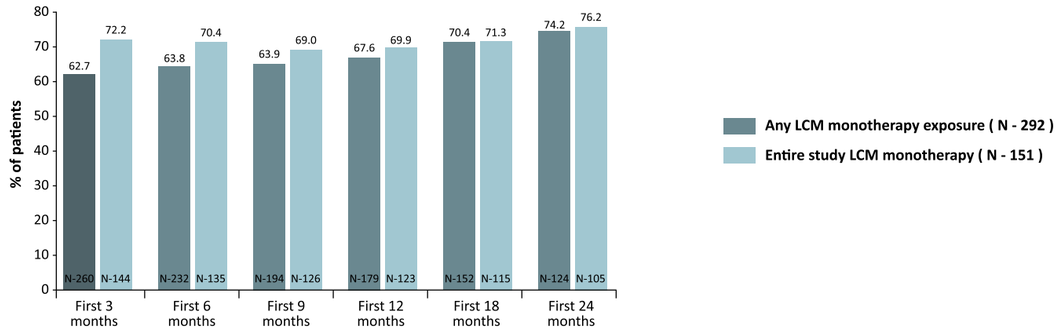
Epilepsia, 2016

1. "Long-term exposure and safety of lacosamide monotherapy for the treatment of partial-onset (focal) seizures: Results from a multicenter, open-label trial"

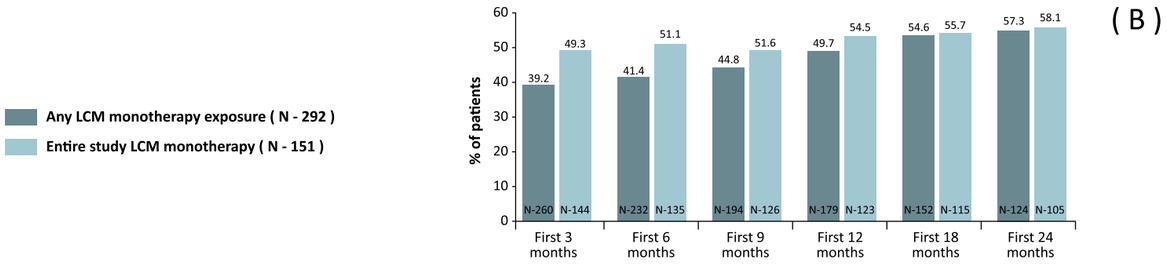
– 322 patients were enrolled in the study.

– Lacosamide administered at a starting dose that was ±100 mg of the ending dose in SP902 (300 or 400 mg/day) & adjusted to ≤800 mg/day, by ≤100 mg/day per week.

(A)



(B)



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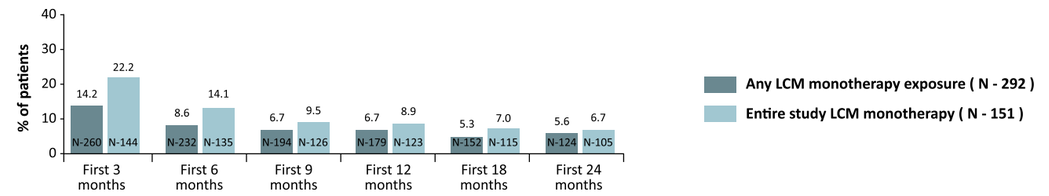


Figure:

Proportion of patients with (A) ≥ 50% reduction, (B) ≥ 75% reduction, or (C) 100% reduction in seizure frequency / 28 days compared with the baseline from SP902.

Conclusion:

Long-term Lacosamide monotherapy (100–800 mg/day) in patients with POS is well tolerated.

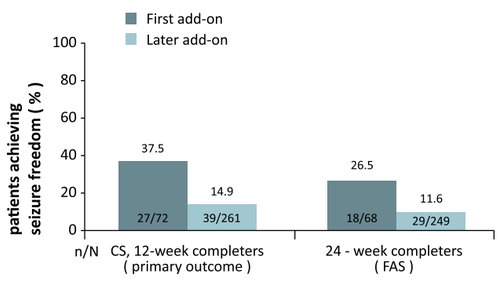
2."Efficacy and safety of lacosamide as first add-on or later adjunctive treatment for uncontrolled partial-onset seizures: A multicenter open-label trial."

Seizure, 2015

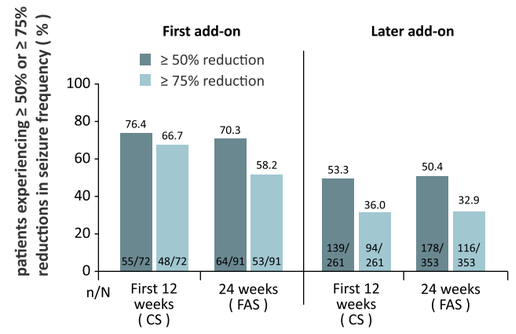
– 456 patients received 1 dose of lacosamide (96 as first add-on, 360 as later add-on).

– During the 6-week Titration Phase, lacosamide was initiated at 100 mg/day (50 mg bid) and then increased by 100 mg/day/week for 4 weeks to a maximum of 400 mg/day (200 mg bid).

(A) Seizure Freedom



(B) Responder Rates



CS, Completer set; FAS, Full analysis set

Figure:

Seizure control, seen as (A) seizure freedom, and (B) responder rates (proportions of patients achieving ≥50% or ≥75% reductions in seizure frequency from Baseline).

Conclusion:

– The results support the use of lacosamide as an efficacious and well-tolerated agent for the early treatment of uncontrolled partial-onset seizures (POS)