achieve a new chance in pediatric epilepsy

Efficacy and Safety of Lacosamide* as Adjunctive Therapy in Subjects ≥1 Month to <4 Years with Partial-onset Seizures

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Why is research in children with epilepsy important?

Today, for epilepsy only a few medications to treat partial-onset seizures have been studied in children – this limits available treatment options for children having this disease.

Lacosamide is approved for adults with partial-onset seizures in the US, EU and other countries. However, data generated in studies with adults cannot just be applied to children.

Children are not small adults.

- Different biology, different presentation of disease and different way their body processes medications
- Clinical research in children helps us to uncover the best effective dose to prevent harmful effects or identify areas of under-treatment
- More data is needed to advance the understanding and treatment of epilepsy in children

*Vimpat® -In the study trial lacosamide syrup

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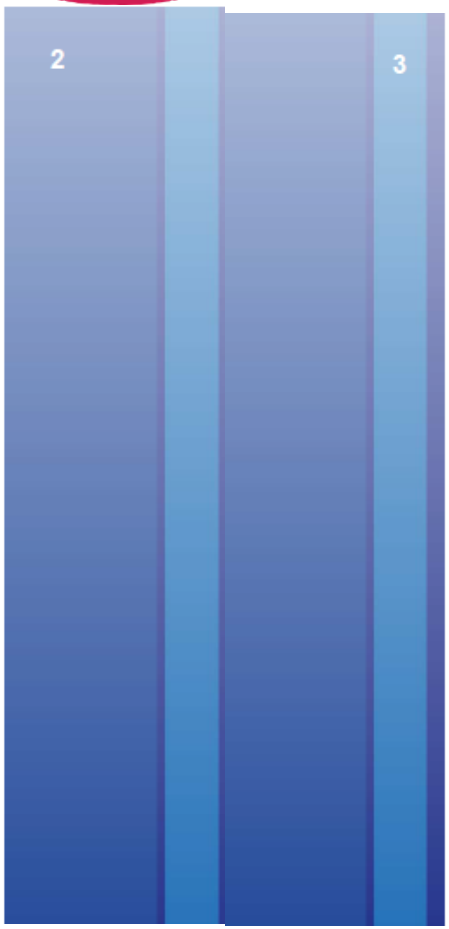
Why consider enrolling my child in this study?

Data from other children studies with different forms of epilepsy suggest that Lacosamide could be a benefit for the treatment of children having partial onset seizures.

As a parent of a child with epilepsy, we need your help by letting your child become a participant in this clinical research study. The study is needed to collect more data on Lacosamide treatment in children to determine if Lacosamide can become a publicly available approved treatment in children.

The effectiveness of Lacosamide is assessed based on how often seizures occur in your child. During the study, we will also capture safety data through blood analyses, questionnaires and physical exams your study doctor will perform.

If you are interested in letting your child participate in the study, your study doctor will give you more information on these assessments and what they will mean for you and your family.



What are the potential benefits and risks?

If you decide to have your child participate in study, you and your child will have the following benefits during the study:

- Personal care from and strong relationships to the study physician and study team to ensure optimal care
- Close monitoring for your child to ensure your child's safety
- Opportunity to help doctors learn more about your child's partial onset seizures and to improve treatment options
- The results of the study might help other families in similar situations in the future

Taking part in a clinical study can also bear risks associated to the treatment procedures and/or the study medication. Your study doctor can inform you about potential side effects or other risks of your child being in this study.

Your child's seizures may improve while participating in this study; however, this cannot be guaranteed.

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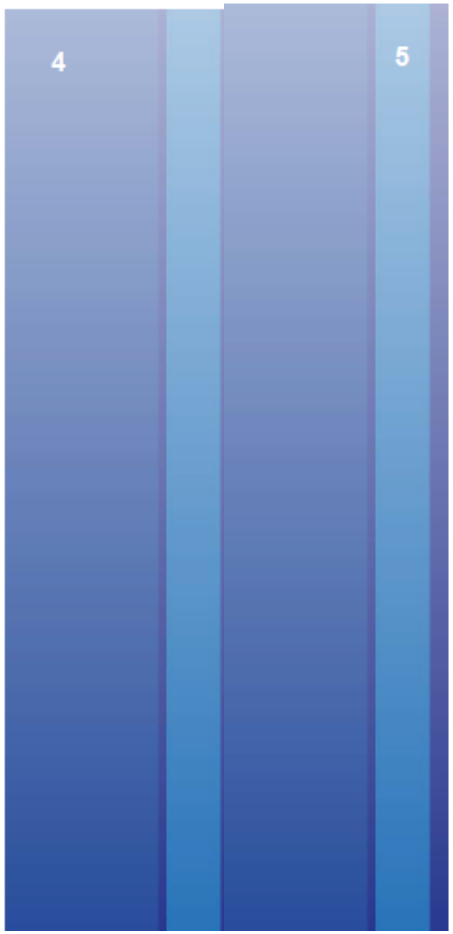
What exactly does the study involve?

The study normally lasts in total up to 93 days, including a 30-day safety follow-up period.

- During that time, you and your child will be asked to attend at least 10 appointments with the study doctor
- Your child will be assigned randomly to one of the two treatment groups. This means there is a 50:50 chance of receiving either Lacosamide or Placebo (dummy drug)
- There will be two hospital stays required for the investigation of the epilepsy status of your child, based on video EEGs
- A clinical research study requires your cooperation. Therefore, it is important that you follow all of the instructions given to you by your study doctor and his/her team
- Please ask your study doctor for accommodation and reimbursement options during the video EEG and options for child care services based on your family situation



How will your participation in the study affect your child's current treatment?

There may be changes to your child's treatment during the study. As a result, the symptoms of your child's disease may be affected.

- Your child's general health will therefore be closely monitored by your study doctor and his/her team
- If necessary, the dosage of the study drug or your child's other medications will be adjusted

Your child will be kept on the dose that suits them best during the study.

After participation in this study, there is the possibility for your child to receive Lacosamide free of charge for up to two years, if you are interested in having your child participate in a follow-up study.

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Creating new prospects

Many people have the desire to discover new things and make a contribution to the welfare of others. By having your child participate in the ACHIEVE study, you are lending your support to an important global health research project.

This is the only way to test and further develop new treatment options and to improve the future lives of children with conditions such as epilepsy, and to better understand how to optimize treatment for children.

We would be delighted if you would consider participation of your child in this study!

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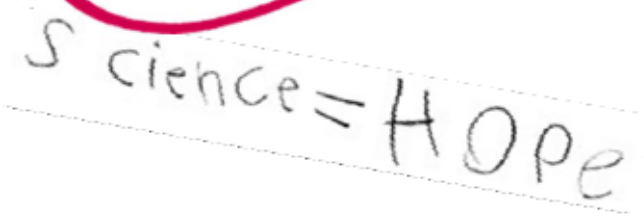

Study doctor's stamp

This leaflet does not replace an informed consent form or an informed consent conversation with your study doctor. **Please speak to your doctor if you'd like more information about participating in this study or have further questions.**

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