

# Levoleucovorin for Autistic Children

Dosage: 1 mg L-Formyl-THF per kg body weight as a solution out of a device

Martin Ulmann / Gerd Wiesler

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Aprofol AG

# Approaching the Underlying Cause of a Disease

a deficiency in a specific organ or in the whole body



Autism spectrum disorder (ASD) is a developmental disability characterized by persistent impairments in social interaction and the presence of restricted, repetitive patterns of behaviors, interests, or activities.

Parents usually notice signs in the first two or three years of their child's life. These signs often develop gradually, though some children with autism reach their developmental milestones at a normal pace and then worsen.

**approximately one in 54 children is diagnosed with an autism spectrum disorder (ASD).**

**ASD is 4.3 times as prevalent among boys as among girls**

*CDC May 2020 (MMRW)*









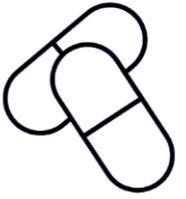

The missing piece, in the brain of affected children!



# 2021 ASD and Language impairment Clinical Trials

Treatment with Levoleucovorin (L-5-Formyl-THF), medication from Aprofol



<p><b>Ph. II</b> with FRA-test</p>	<p><b>Dr. R. Frye</b> Phoenix Children's Hospital</p> 	<p><b>Award from</b></p> 	<p><b>2 x 80</b> children  <b>40</b> Patients dosed</p> <p><b>2.5 - 5 y</b> age <b>40</b> Patients placebo</p>	<p><b>1 mg</b> /kg/day </p> <p><b>25 mg</b> Max per day</p>
<p><b>Ph. II</b> without FRA-test</p>		<p><b>Award from</b></p> 		
<p><b>Ph. II</b></p>	<p><b>Dr. L. Scahill</b> Emory University</p> 	<p><b>Award from</b></p> 	<p><b>162</b> children  <b>81</b> (20 / 61) Patients dosed</p> <p><b>5 - 12 y</b> age <b>81</b> Patients placebo</p>	<p> → </p> <p><b>2 mg</b> → <b>1 mg</b> 2 x Day</p> <p><b>50</b> → <b>25 mg</b> Max per day</p>



# Medication: Convenient Application of a Levoleucovorin-solution in a device which allows a precise dosing based on body weight (1 mg per kg)

Use of a Levoleucovorin solution which can be easily divided in the requested doses  
(=> Taking care on the saturation of the Absorption / Pharmacokinetics)

Use of a 25 mg per mL solution of Levofolinic acid

Divide it into the individual doses required by the patient  
(mg/kg body weight)

Add the individual dose to a drinks and provide it to the patient  
(two times a day)

**Dosing device:**

Novelia<sup>®</sup> 40  $\mu$ L is able to provide 1.0 mg API per drop

Designed to avoid contamination (no preservative necessary)

consistent drop size (+/- 5 %)

=> Approved for preservative free eye drops (convenient)





# Further Information

## «One-Carbon Metabolism Abnormalities in Autism Spectrum Disorder»

Lecture by **Dr. Richard E. Frye** on occasion of the 13th International Conference One-Carbon Metabolism on Tuesday, September 14, 2021, 14:30 – 15:00 h  
For details <https://www.homocysteine2021.org/program>



For further information please visit

[www.aprofol.com](http://www.aprofol.com)

Aprofol AG  
CH-9050 Appenzell  
[info@aprofol.com](mailto:info@aprofol.com)



**Martin Ulmann**  
Founder & CEO  
[martin.ulmann@aprofol.com](mailto:martin.ulmann@aprofol.com)

or contact us



**Gerd Wiesler**  
Head of Operations  
[gerd.wiesler@aprofol.com](mailto:gerd.wiesler@aprofol.com)