

# How much is too much when the pediatric minimal alcohol dose for toxicity is unknown?

## FDA PEDIATRIC GUIDELINES

1. The FDA has set a maximum **limit of 0.5% ethanol** in oral over-the-counter products intended for children younger than age **6 years**<sup>1</sup>
2. The American Academy of Pediatrics Committee on Drugs has recommended that the amount of ethanol contained in any preparation **should not be able to produce a blood concentration >25 mg/dL** after a single dose<sup>2</sup>



# Alcohol level leading to toxicity in pediatrics is unknown<sup>1</sup>



## Ethanol Pharmacokinetics in Neonates and Infants

- Pharmacokinetics, pharmacodynamics, and safety of ethanol **in this vulnerable population** have not been well characterized<sup>3</sup>
- There remains a lack of evidence of the adverse events of ethanol in the developing brain of infants. Due to the lack of evidence on how ethanol affects developing brains, clear recommendations are impossible at this time, but it seems reasonable for clinicians to minimize the use of ethanol-containing solutions in neonates whenever possible.<sup>3</sup>

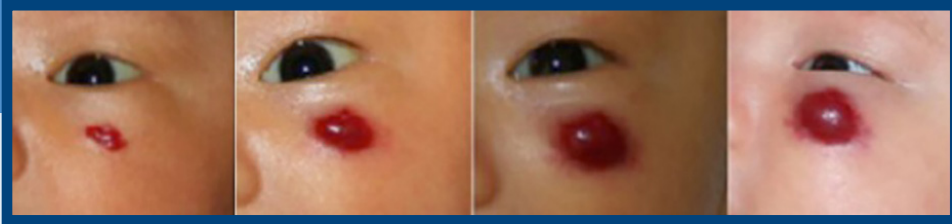


Since the activity of alcohol dehydrogenase is immature, clearance of ethanol is reduced and, as a consequence, after administration, its accumulation is largely observed in the plasma<sup>4</sup>

Newborns, infants, and children are not able to metabolize ethanol as efficiently as adults; as a consequence, they may be at higher risk of both acute and chronic alcohol-related toxicities.<sup>4</sup>

- The use of ethanol in pediatric pharmaceutical preparations raises some concerns since it can be harmful either for possible acute toxicity after accidental overdose or for potential chronic toxicity, with prolonged medicinal exposure for treatment of pediatric chronic diseases<sup>4</sup>

# Proliferating Infantile Hemangioma Won't Wait



HEMANGEOL® (propranolol hydrochloride) oral solution is indicated for the treatment of proliferating infantile hemangioma requiring systemic therapy.

## Important Safety Information

### CONTRAINDICATIONS

HEMANGEOL® (propranolol hydrochloride) is contraindicated in the following conditions:

- Premature infants with corrected age <5 weeks
- Infants weighing less than 2 kg
- Known hypersensitivity to propranolol or any of the excipients
- Asthma or history of bronchospasm
- Heart rate < 80 beats per minute, greater than first-degree heart block, or decompensated heart failure
- Blood pressure < 50/30 mmHg
- Pheochromocytoma

### WARNINGS AND PRECAUTIONS

HEMANGEOL® prevents the response of endogenous catecholamines to correct hypoglycemia and masks the adrenergic warning signs of hypoglycemia, particularly tachycardia, palpitations, and sweating.

HEMANGEOL® can cause hypoglycemia in children, especially when they are not feeding regularly or are vomiting; withhold the dose under these conditions. Hypoglycemia may present in the form of seizures, lethargy, or coma. If a child has clinical signs of hypoglycemia, parents should discontinue HEMANGEOL® and call their health care provider immediately or take the child to the emergency room. HEMANGEOL® may cause or worsen bradycardia or hypotension. Monitor heart rate and blood pressure after treatment initiation or increase in dose. Discontinue treatment if severe (<80 beats per minute) or symptomatic bradycardia or hypotension (systolic blood pressure <50 mmHg) occurs. HEMANGEOL® can cause bronchospasm; do not use in patients with asthma or a history of bronchospasm. Interrupt treatment in the event of a lower respiratory tract infection associated with dyspnea and wheezing. HEMANGEOL® may worsen circulatory function in patients with congestive heart failure or increase the risk of stroke in PHACE syndrome patients with severe cerebrovascular anomalies. Investigate infants with large facial infantile hemangioma for potential arteriopathy associated with PHACE syndrome prior to HEMANGEOL® therapy. HEMANGEOL® will interfere with epinephrine used to treat serious anaphylaxis.

### ADVERSE REACTIONS

The most frequently reported adverse reactions to HEMANGEOL® were sleep disorders, aggravated respiratory tract infections, diarrhea, and vomiting. Adverse reactions led to treatment discontinuation in fewer than 2% of treated patients. Adverse events such as cardiac disorders, urticaria, alopecia, hypoglycemia, and bradycardia occurred in less than 1%. Safety and effectiveness for infantile hemangioma have not been established in pediatric patients greater than 1 year of age.

Please see accompanying Full Prescribing Information or visit [www.hemangeol.com](http://www.hemangeol.com)



**Hemangeol®:**  
**No pediatric ethanol exposure**



- ✓ **Alcohol FREE**
- ✓ **Designed for infants**
- ✓ **FDA-approved**