

Hemangeol[®]
(propranolol hydrochloride)
oral solution 4.28 mg/mL



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The **Only FDA-Approved** Medication For Proliferating Infantile Hemangioma Requiring A Systemic Therapy

Covered by majority of commercial healthcare plans. Co-Pay Savings Program and 24-hour caregiver support available

Please see Important Safety Information on page 7 and accompanying Full Prescribing Information.



Hemangeol[®]
(propranolol hydrochloride)
oral solution 4.28 mg/mL



Designed for infant acceptability¹

- Strawberry and vanilla flavor
- May be added to milk or fruit juice
- Specially developed oral syringe to facilitate administration

Formulated for infants¹

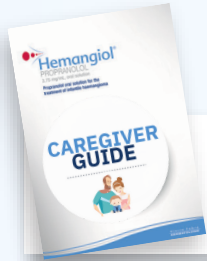
- Alcohol free
- Sugar free
- Paraben free

Safety and efficacy¹

- Twice daily dosage
- 60% complete or near complete resolution at 6 months
- <2% patients discontinued treatment due to adverse reactions

Parent support

- Parent information material



1. Hemangeol product information. Hemangeol [Full Prescribing Information]. Parsippany, NJ: Pierre Fabre Pharmaceuticals, Inc.; 2021



Indication¹

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

Initiate treatment at ages 5 weeks to 5 months

Contraindications

HEMANGEOL 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

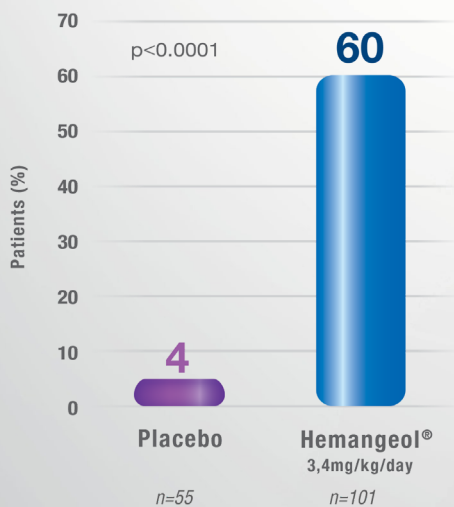
Pictures source : Pierre Fabre Pharma Inc.

Please see additional Important Safety Information on page 7 and accompanying Full Prescribing Information.

60 % of success at week 24²
versus placebo 4%

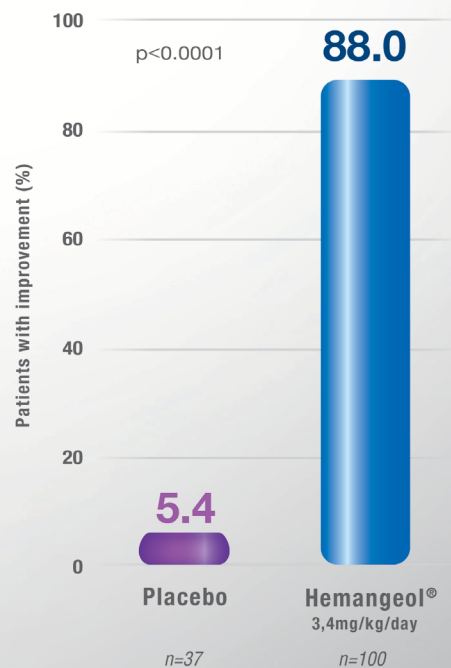
A randomized, double-blind study in infants, aged 35 days to 5 months at inclusion, with proliferating infantile hemangiomas (IH) requiring systemic therapy y (excluding life-threatening IH, function-threatening IH, and ulcerated IH with pain and lack of response to simple wound care measures) compared regimens of HEMANGEOL to placebo

Primary endpoint - Complete or nearly complete resolution at week 24⁽¹⁾



88% of patients had improvement¹
at week 5 of treatment versus placebo 5.4%

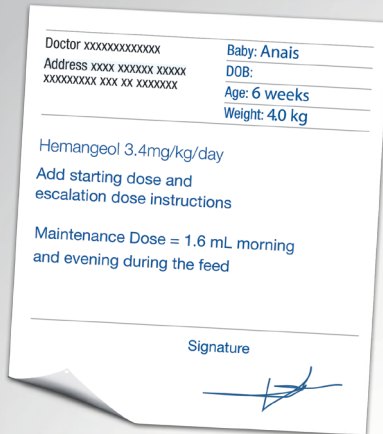
Secondary endpoint - Improvement at week 5



2. C. LEAUTE-LABREZE et al. A Randomized, Controlled Trial of Oral Propranolol in Infantile Hemangioma. N Engl J Med 2015;372:735-46. Please see additional Important Safety Information on page 7 and accompanying Full Prescribing Information.

BEFORE STARTING HEMANGEOL TREATMENT

How to prescribe?



WARNINGS AND PRECAUTIONS

1• HYPOGLYCEMIA

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.

2• BRADYCARDIA AND HYPOTENSION

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.

Please see additional Important Safety Information on page 7 and accompanying Full Prescribing Information.

How to administer?



DIRECTLY INTO THE MOUTH

IF NECESSARY



DILUTED IN SMALL QUANTITY OF MILK



DILUTED IN SMALL QUANTITY OF ADAPTED FRUIT JUICE

3• BRONCHOSPASM

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.

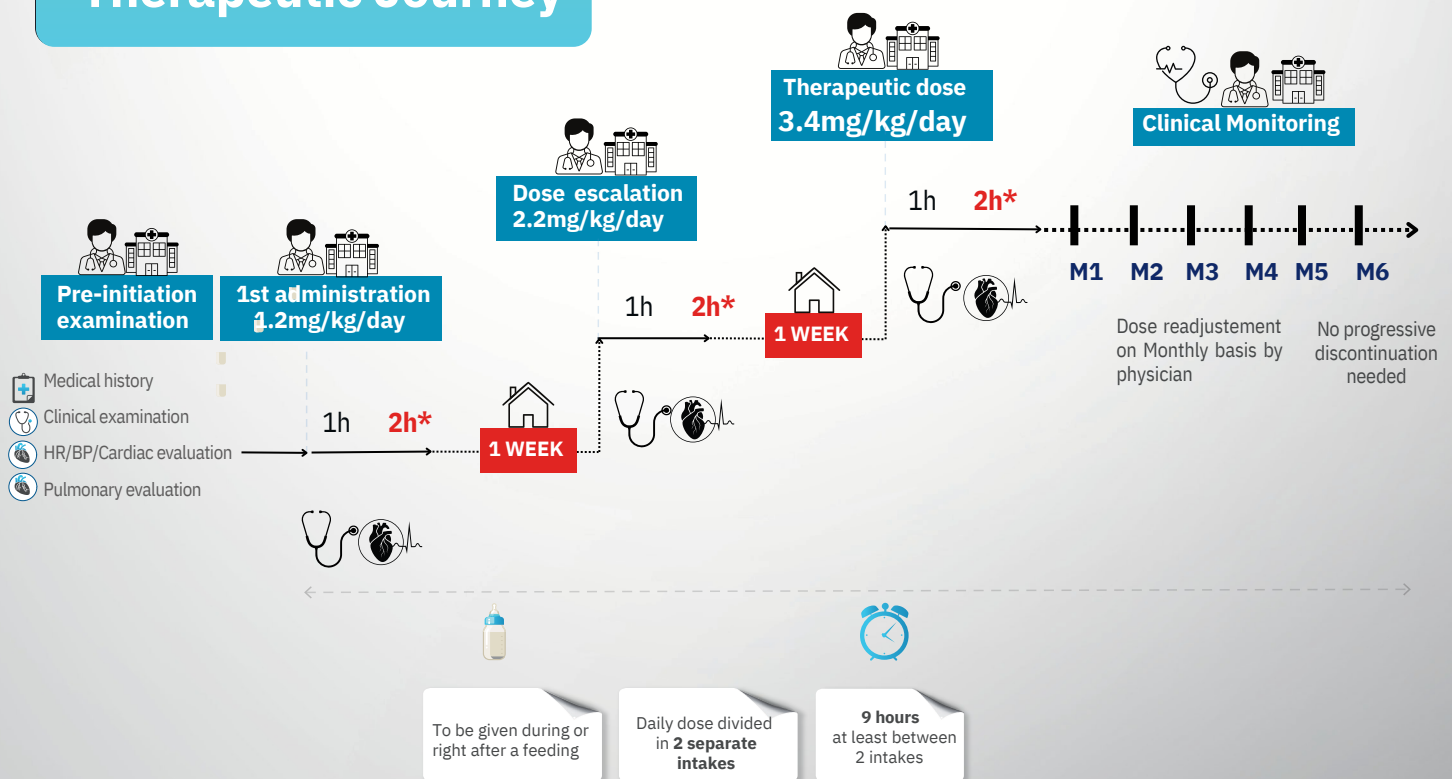
4• CARDIAC FAILURE AND INCREASED RISK OF STROKE IN PHACE SYNDROME

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.

5• HYPERSENSITIVITY

HEMANGEOL will interfere with epinephrine used to treat serious anaphylaxis

Therapeutic Journey



* After the first intake and each dose increase, monitor HR and BP for 2 hours.

DURING HEMANGEOL TREATMENT

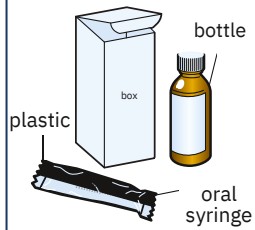
Instructions for use

Adapted from Instructions for Use approved by the U.S. Food and Drug Administration

1

Remove the items from the box

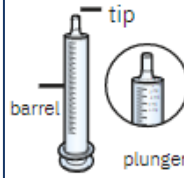
- Place your box of supplies on a clean flat work surface, such as a table.
- Remove the HEMANGEOL® bottle and oral dosing syringe from the box.
- Do not shake the bottle before use.**
- Keep the box for storage.



2

Check the dose

- Remove the oral dosing syringe from the plastic bag.
- Safely throw the plastic bag away.
- The barrel of the syringe has markings in milliliters (mL).
- Look at the markings on the barrel of the oral dosing syringe and find the mL marking that matches the HEMANGEOL dose in mL prescribed by your doctor.



3

Open the bottle

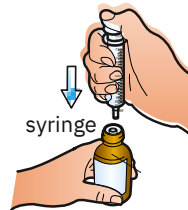
- Open the bottle of HEMANGEOL by pushing down on the plastic cap while turning the cap to the left.
- Write down on the box the date when you first open the bottle.



4

Insert the syringe

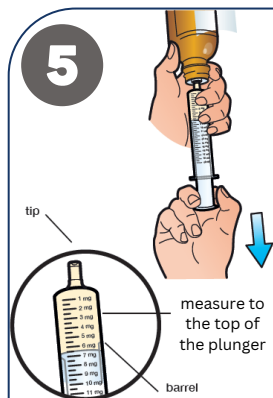
- Place the bottle on your work surface. Use one hand to hold the bottle upright. Use your other hand to insert the tip of the oral dosing syringe into the syringe adapter at the top of the bottle. Push the plunger all the way down.
- Do not remove the syringe adapter. If the syringe adapter is missing talk to your pharmacist.



5

Remove the dose

- Use one hand to hold the oral dosing syringe in place.
- With your other hand, turn the bottle upside down.
- Pull back on the plunger until the top of the plunger lines up with the marking on the barrel of the syringe that matches the dose of HEMANGEOL prescribed by your doctor. Your child's dose may be different than the dose shown in this picture.



6

Check for air bubbles

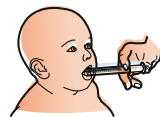
- Check for air bubbles in the oral dosing syringe.
- If you see air bubbles, push up on the plunger towards the bottle just enough to remove any large air bubbles and then pull back to the measured dose.



8

Give HEMANGEOL to your child

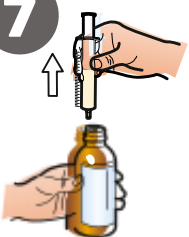
- Slowly squirt HEMANGEOL into your child's mouth after placing the oral dosing syringe against the inside of the cheek.
- Keep your child in an upright position for a few minutes right after giving a dose of HEMANGEOL.
- If needed, you can dilute the dose of HEMANGEOL in a small amount of milk or fruit juice and give it to your child in a baby's bottle. If your child spits up a dose or if you are not sure your child got all of the medicine, do not give another dose. Wait until the next scheduled dose.



7

Remove the syringe

- Turn bottle upright again and place it on your work surface. Remove the oral dosing syringe from the bottle. Do not push the plunger in during this step.
- The syringe adapter should stay attached to the bottle.



9

Close the bottle

- Replace the plastic cap on the bottle by turning it clock-wise (to the right).



10

Clean the syringe

- Clean the oral dosing syringe after each use by rinsing with clean tap water.
- Do not take apart the oral dosing syringe.
- Do not use any soap or alcohol based product to clean. Wipe the outside dry.
- Do not put the oral dosing syringe through a sterilizer or dishwasher.



Instrucciones de Uso

Adaptado de las instrucciones de uso aprobadas por la U.S. Food and Drug Administration

1

Retire los artículos de la caja

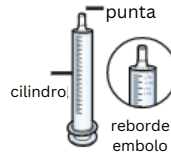
- Coloque su caja de suministros sobre una superficie de trabajo limpia y plana, como una mesa.
- Saque el frasco de HEMANGEOL® y la jeringa de dosificación oral de la caja. **No agite la botella antes de usar.** Guarde la caja para el almacenamiento.



2

Confirme la dosis

- Retire la jeringa de dosificación oral de la bolsa plástica.
- Deseche la bolsa plástica de forma segura. El cilindro de la jeringa tiene marcas en mililitros (mL).
- Examine las marcas en el cilindro de la jeringa de dosificación oral y encuentre la marca en mL que coincida con la dosis de HEMANGEOL en mL prescrita por su médico.



3

Abra la botella

- Abra la botella de HEMANGEOL presionando hacia abajo la tapa de plástico mientras gira la tapa hacia la izquierda.
- Escriba en la caja la fecha en que abrió la botella por primera vez.



4

Inserte la jeringa

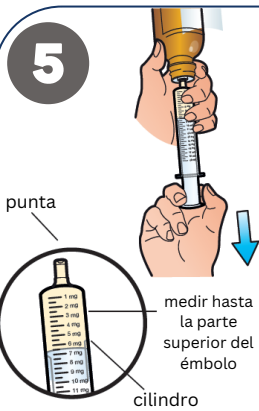
- Coloque la botella en su superficie de trabajo. Use una mano para sostener la botella en posición vertical. Use su otra mano para insertar la punta de la jeringa de dosificación oral en el adaptador de jeringa en la parte superior de la botella. Empuje el émbolo hasta el fondo.
- No retire el adaptador de la jeringa. Si falta el adaptador de la jeringa, hable con su farmacéutico.



5

Retire la dosis

- Use una mano para sujetar la jeringa de dosificación oral en su lugar. Con la otra mano, dé la vuelta a la botella.
- Tire del émbolo hacia atrás hasta que la parte superior del émbolo se alinee con la marca en el cilindro de la jeringa que coincida con la dosis de HEMANGEOL recetada por su médico. La dosis de su hijo puede ser diferente a la dosis que se muestra en esta imagen.



6

Buscar burbujas de aire

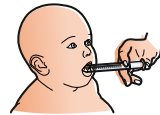
- Compruebe si hay burbujas de aire en la jeringa de dosificación oral. Si ve burbujas de aire, empuje el émbolo hacia la botella lo suficiente como para eliminar las burbujas de aire grandes y luego tire hacia atrás hasta la dosis medida.



8

Dar HEMANGEOL a su hijo

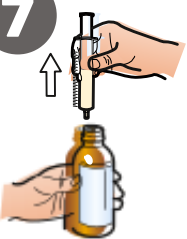
- Administre lentamente el HEMANGEOL en la boca de su hijo después de colocar la jeringa de dosificación oral contra el interior de la mejilla oprimiendo el émbolo.
- Mantenga a su hijo en posición erguida durante unos minutos inmediatamente después de administrar una dosis de HEMANGEOL.
- Si es necesario, puede diluir la dosis de HEMANGEOL en una pequeña cantidad de leche o jugo de frutas y dársela a su hijo en un biberón. Si su hijo escupe una dosis o si no está seguro de si recibió todo el medicamento, no le dé otra dosis. Espere hasta la siguiente dosis programada.



7

Retire la jeringa

- Ponga el frasco en posición vertical de nuevo y colóquelo sobre su superficie de trabajo.
- Retire la jeringa dosificadora oral del frasco. No empuje el émbolo durante este paso.
- El adaptador de jeringa debe permanecer unido al frasco.



9

Cerrar la botella

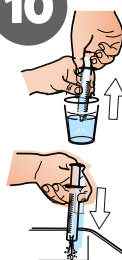
- Vuelva a colocar la tapa de plástico en la botella girándola en el sentido de las agujas del reloj (hacia la derecha).



10

Limpiar la jeringa

- Limpie la jeringa de dosificación oral después de cada uso enjuagándola con agua limpia del grifo.
- No desarme la jeringa de dosificación oral.
- No use ningún jabón o producto a base de alcohol para limpiar. Seque el exterior.
- No coloque la jeringa dosificadora oral en un esterilizador o lavavajillas.



Safety profile¹

Caregiver education is essential



ADVERSE REACTIONS

The most frequently reported adverse reaction (>10%) in infants treated with 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.



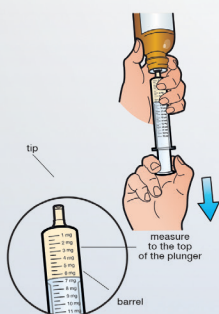
1. Hemangeol product information

Please see additional Important Safety Information on page 7 and accompanying Full Prescribing Information.

Keep in mind: The “PACT”

Preparing

The dose prescribed by the physician



Always use the **specific oral syringe** provided in the box

Administering

With the specific oral syringe

During or right after feeding



Skip the dose if the child is not eating or is vomiting

Checking

Potential serious side effects:

- Hypoglycemia. Risk is increased with poor feeding, vomiting, infections, and increased glucose demands
- Worsening bradycardia or hypotension
- Bronchospasm
- Cardiac failure in patients with congestive heart failure
- Increased risk of stroke in PHACE syndrome



Call physician if necessary

Adjusting the Treatment

Regular visits with physician to:

- Adjust the dose based on child's weight increase
- Monitor child's condition.

Always monitor HR and BP for 2 hours after initiation or dose increase



DURING HEMANGEOL TREATMENT

Duration¹ of treatment

- HEMANGEOL should be administered for a 6 month period.
- Discontinuation of treatment **does not require a progressive decrease in the dose.**
- In the minority of patients showing a relapse of symptoms after treatment discontinuation, **treatment may be re-initiated.**

Product characteristics

Designed for infants
Propranolol hydrochloride 4.28mg/mL

Shelf-life:

- Before opening: 3 years • After first opening: 2 months

Formulated for infants

- Alcohol free
- Sugar free
- Paraben free



1. Hemangeol product information

Hemangeol[®]

(propranolol hydrochloride)
oral solution **4.28 mg/mL**

IMPORTANT SAFETY INFORMATION

Do not give HEMANGEOL[®] to your child if your child:

- was born prematurely and has not reached the corrected age of 5 weeks
- weighs less than 4 ½ pounds
- is allergic to propranolol or any of the other ingredients in HEMANGEOL[®]
- has asthma or a history of breathing problems
- has a heart problem, slow heart rate (less than 80 heart beats per minute), very low blood pressure
- is at risk for low blood sugar, for example is vomiting or unable to take feedings
- has high blood pressure caused by a tumor on the adrenal gland, called “pheochromocytoma”

Tell your doctor about all of your child’s medical conditions, all of the medicines your child takes, and all of the medicines that you take if you are breastfeeding your child.

HEMANGEOL[®] can cause serious side effects, including:

Low blood sugar (hypoglycemia), especially if your child is not taking feedings, or is vomiting. HEMANGEOL[®] may make it more difficult to recognize the signs and symptoms of low blood sugar in your child. **To help reduce the risk of low blood sugar with HEMANGEOL[®]**, give HEMANGEOL[®] during or shortly after feeding your child. Feed your child regularly during treatment. Tell your doctor if your child has a poor appetite. If your child is not taking feedings, due to an illness

or vomiting, do not give HEMANGEOL[®] until your child is taking feedings normally again.

If your child has any of the signs or symptoms of low blood sugar listed below during treatment with HEMANGEOL[®], stop giving your child HEMANGEOL[®] and call your doctor or go to the nearest emergency room right away. If your child is conscious, give him/her a drink of a liquid containing sugar.

Signs or symptoms of low blood sugar include: pale, blue or purple skin color, sweating, irritability, crying for no apparent reason, irregular or fast heartbeat, poor feeding, low body temperature, unusual sleepiness, seizures, breathing stops for short periods of time, and loss of consciousness.

Other serious side effects can include:

- **New or worsening slow heart rate (bradycardia) or low blood pressure (hypotension).**
- **Breathing problems or wheezing.**
- **Stroke.** HEMANGEOL[®] may increase the risk of stroke in certain children who have severe problems with the blood vessels in their brain, particularly if your child has a large hemangioma that affects the face or head.

Call your doctor or go to the nearest hospital emergency room if your child has:

- pale skin color, slow or uneven heartbeats, arms or legs feel cold, blue or purple skin color, or fainting.
- breathing problems or wheezing during treatment with HEMANGEOL[®].

The most common side effects include: sleep problems, worsening respiratory tract infections, diarrhea, and vomiting. These are not all the possible side effects of HEMANGEOL[®]. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see [Full Prescribing Information](#) and [Medication Guide](#).