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

A Guide for Parents and Caregivers

Treat IH Early With HEMANGEOL®



The first and only FDA-approved treatment for proliferating infantile hemangioma (IH). If your baby has been diagnosed with IH, you may already know it can change quickly. This brochure can help you understand why early treatment matters, what to expect from HEMANGEOL®, and how to get support.

Not an actual patient.

FDA, US Food and Drug Administration.

USE

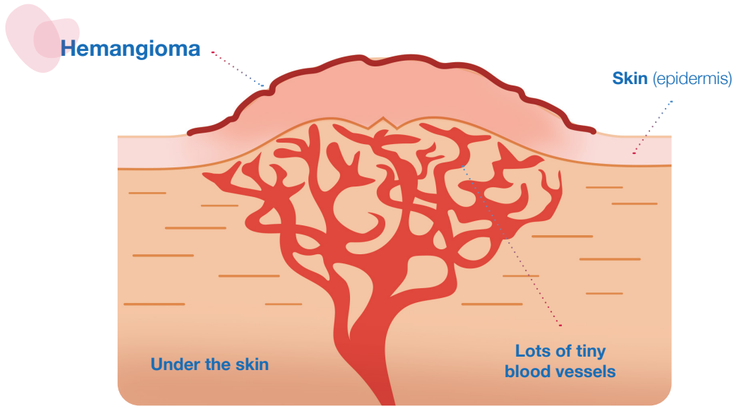
HEMANGEOL (propranolol hydrochloride) oral solution is a prescription medicine used to treat proliferating infantile hemangioma (a type of birthmark) requiring treatment throughout the body.

Please see Important Safety Information continued on following pages, as well as full Important Safety Information on pages 14-15. Please see accompanying full Prescribing Information and Medication Guide.

What Should I Know About IH?

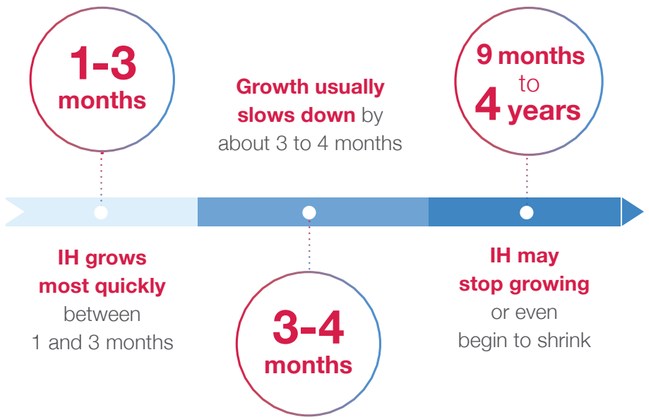
Hemangeol® (propranolol hydrochloride) oral solution 4.28 mg/mL

Infantile hemangioma (IH) is a common type of benign tumor—benign means it's ***not*** cancerous. IH develops when blood vessels grow and form in an unusual way. IH isn't always visible at birth, but it might appear when your baby is a few weeks old.



IH usually grows in a predictable way

At first, an IH grows quickly. Then it slows down, stops growing, and may even get smaller over time.

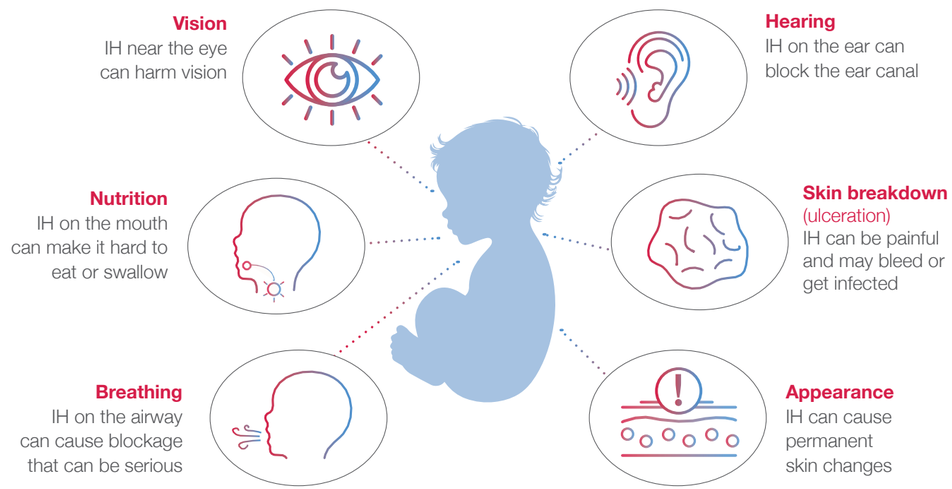


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Why Did My Doctor Recommend Treatment?

Many IHs are harmless, but some require treatment. Doctors might recommend treatment if an IH could cause complications. These complications could interfere with your baby's healthy development.

IH Can Lead to Complications



The larger an IH gets, the higher the risk of complications.

Treatment can help slow the growth or shrink the IH before complications occur.



Not an actual patient.

Q: If IHs tend to get smaller on their own, why does my child need medication?

A: Treating IH early matters. Waiting too long to see a specialist or start treatment can limit how well treatment works.

HEMANGEOL® (propranolol hydrochloride) oral solution: A Medicine Made for IH

HEMANGEOL® is a prescription medicine that is used to treat proliferating (growing) **IH.**
It's given orally so that it treats IH from inside the body.



Not an actual patient.

Is HEMANGEOL® formulated for babies?
HEMANGEOL® was made specifically for infants and has been helping babies with IH for more than 12 years. HEMANGEOL® is the **only FDA-approved treatment for proliferating IH**. There is no generic version or approved therapeutic equivalent.

What's in HEMANGEOL®? Propranolol is the active ingredient in HEMANGEOL®.

Why the formula matters: Propranolol is used to treat IH, but it is also sometimes used in medications for other conditions, like high blood pressure in adults. Those medications are different formulations from HEMANGEOL®, which is specifically formulated for use in children.

Brand-name HEMANGEOL® is alcohol-free and formulated specifically for infants.

Who should NOT take HEMANGEOL?

Do not give HEMANGEOL to your child if they:

- Were born early and are less than 5 weeks corrected age
- Weigh less than 4.5 lbs
- Have asthma or a history of breathing problems (bronchospasm)
- Have certain heart conditions (such as slow heart rate, heart block, or heart failure)

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How Quickly Can I Expect HEMANGEOL® to Work?

HEMANGEOL® was **studied in a clinical trial that included 460 babies** with proliferating hemangiomas.

60% of babies treated were clear or almost clear

60% (6 out of 10) **of babies treated with HEMANGEOL®** had their **IH completely or nearly completely cleared after 24 weeks**, compared with 4% of babies who received no treatment.*



These photos are of actual patients treated with HEMANGEOL® in clinical trials. Individual results vary.

- In the same study, **88%** (nearly 9 out of 10) of the babies treated with HEMANGEOL® showed **improvement by 5 weeks**, compared with 5% of babies who received no treatment
- In another study of 23 babies treated with HEMANGEOL®, **36%** of babies had their **IH resolved by 3 months**

*Of patients on HEMANGEOL® 3.4 mg/kg/day for 6 months who were considered successes, 10% required retreatment for recurrence of hemangiomas.

Who should NOT take HEMANGEOL? (continued)

Do not give HEMANGEOL to your child if they:

- Have very low blood pressure
- Have high blood pressure caused by a tumor on the adrenal gland, called "pheochromocytoma"
- Are allergic to propranolol or any of the ingredients in HEMANGEOL

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

How to Give HEMANGEOL®

(propranolol hydrochloride) oral solution

Your baby's doctor will choose the right dose and adjust it as your baby grows.
It's important to follow the instructions exactly. Here are some dosing basics to remember:

Do give HEMANGEOL® **twice a day**, with doses **at least 9 hours apart**.

Do give HEMANGEOL® **during** a feeding or **right after** a feeding.

Don't give an extra dose if your baby spits up or if you're not sure they got all the medicine. **Wait until the next scheduled dose.**

Don't shake the bottle before giving a dose.

See pages 10-11 for step-by-step instructions for how to give HEMANGEOL® (pages 12-13 in Spanish).

Important Safety Information for HEMANGEOL

HEMANGEOL may cause serious side effects, including:

Low blood sugar (hypoglycemia), which can be serious and may lead to seizures, loss of consciousness, or even death. This is more likely if your child is not eating well, is vomiting, or is sick. Always give HEMANGEOL during or right after feeding. Do not give a dose if your child is not eating. Signs of low blood sugar may include pale skin, sweating, irritability, unusual sleepiness, or seizures.

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Possible Side Effects

Like most medicines, HEMANGEOL® can cause side effects. In clinical trials, the most common side effects (greater than 10%) were sleep problems, worsening respiratory tract infections, diarrhea, and vomiting. In the clinical study:

fewer than **2%** of patients stopped treatment due to side effects.

less than **1%** had cardiac (heart-related) side effects.

HEMANGEOL® has important safety risks that you should be aware of:

Low blood sugar (hypoglycemia)

- To help reduce the risk of low blood sugar, give HEMANGEOL® during a feeding or right after a feeding. Skip the dose if your baby is not eating or is vomiting. If you notice signs or symptoms of low blood sugar, stop giving HEMANGEOL® and call your doctor immediately or go to the emergency room
- Possible signs and symptoms of low blood sugar include pale, blue, or purple skin, sweating, unusual irritability and crying, fast or uneven heartbeat, poor feeding, low body temperature, unusual sleepiness, seizures, pauses in breathing, or fainting

Slow heart rate or low blood pressure

- Your baby's healthcare provider may monitor heart rate and blood pressure. Call your doctor 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

- HEMANGEOL® can cause spasms of your child's airway. Call your doctor immediately or go to the emergency room if your child has breathing problems or wheezing during treatment

If you notice any of the warning signs or symptoms listed above, or if you are worried, contact your baby's healthcare provider right away or go to the emergency room.

Important Safety Information for HEMANGEOL (continued)

Bradycardia and hypotension. HEMANGEOL may slow your child's heart rate or lower their blood pressure. Call your healthcare provider if your child seems unusually tired, dizzy, faints, or has pale or cold skin.

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How to Get Your Prescription for HEMANGEOL®
(propranolol hydrochloride) oral solution

HEMANGEOL® prescriptions are filled through Anovo®, the specialty pharmacy provider for HEMANGEOL®. A specialty pharmacy focuses on certain medicines that may need extra support—like help with insurance and getting your medicine delivered.

When your doctor sends your prescription to our specialty pharmacy Anovo, this is what you can expect:

1. **Welcome Call** from your Care Coordinator to verify your prescription, offer support, and answer questions.
2. **Insurance Verification** to review coverage and benefits.
3. **Financial Assistance Review** to explore copay programs and other support options.
4. **Medication Delivery** with instructions and product-specific information.
5. **Ongoing Pharmacy Support**, including refill coordination, reminders, and 24/7 access to a pharmacist.
6. **Nurse Ambassador Support** to help you and your child stay on track with treatment, answer health or medication questions, and provide regular check-ins by phone.



Not an actual patient.

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Eton Cares Program®

When your doctor prescribes HEMANGEOL®, you're automatically enrolled in the **Eton Cares Program**.



For questions or support, please contact us at our specialty pharmacy Anovo:

For Anovo's Care Team, call

1-833-486-5950

Monday-Friday 8:00 AM-5:00 PM CT.

Anovo's Pharmacy Team is always available by phone **24 hours a day, 365 days a year**.

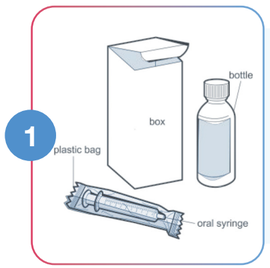
A helpful tip: We recommend saving Anovo's phone number in your contacts, so you can easily recognize important calls about your prescription, refills, or insurance updates.

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How to Use HEMANGEOL®

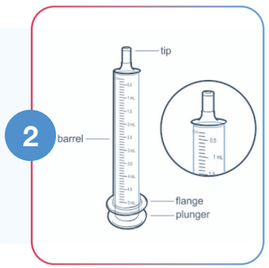
(propranolol hydrochloride) oral solution

Adapted from Instructions for Use **approved by the FDA**



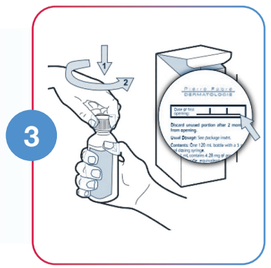
Remove the items from the box

- 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



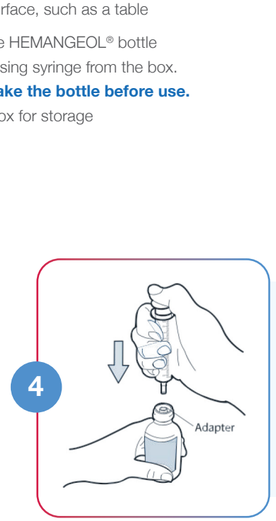
Check the dose

- 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



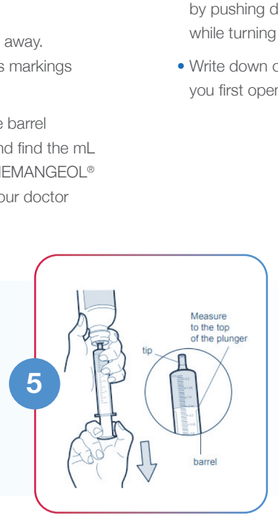
Open the bottle

- 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



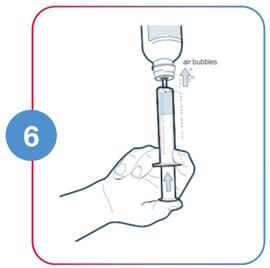
Insert the syringe

- 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



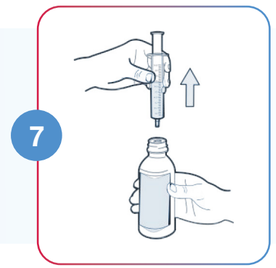
Remove the dose

- 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



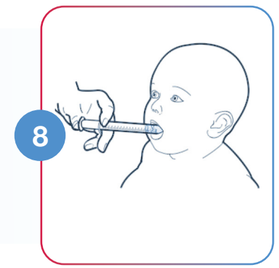
Check for air bubbles

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



Remove the syringe

- Turn the 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



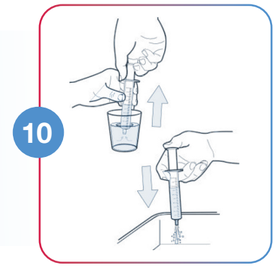
Give HEMANGEOL® to your child

- 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



Close the bottle

- Replace the plastic cap on the bottle by turning it clockwise (to the right)



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

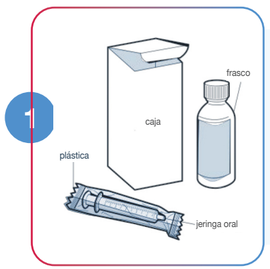
Hemangeol®
(propranolol hydrochloride)
oral solution 4.28 mg/mL

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Cómo usar HEMANGEOL®

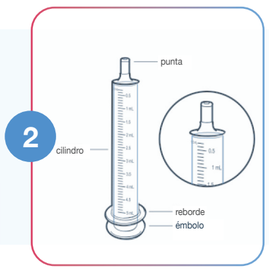
(propranolol hydrochloride) oral solution

Adaptado de las instrucciones de uso **aprobadas por la FDA**



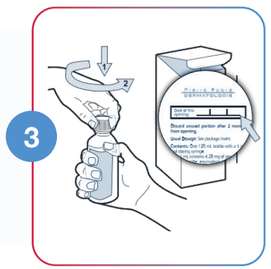
Retire los artículos de la caja

- 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



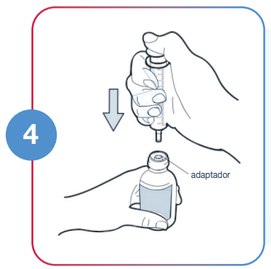
Confirme la dosis

- 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



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



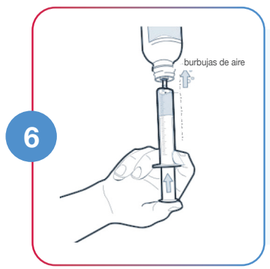
Inserte la jeringa

- 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



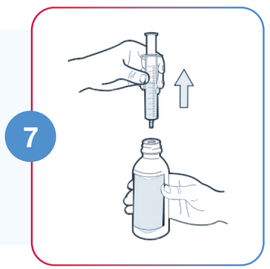
Retire la dosis

- 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



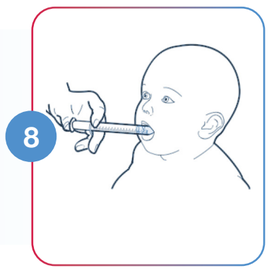
Buscar burbujas de aire

- 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



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



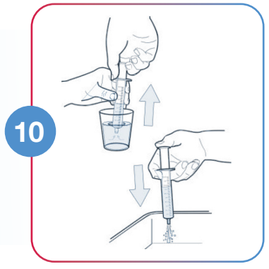
Dar HEMANGEOL® a su hijo

- 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



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)



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

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Important Safety Information for HEMANGEOL®
(propranolol hydrochloride) oral solution

USE

HEMANGEOL (propranolol hydrochloride) oral solution is a prescription medicine used to treat proliferating infantile hemangioma (a type of birthmark) requiring treatment throughout the body.

Who should NOT take HEMANGEOL?

Do not give HEMANGEOL to your child if they:

- Were born early and are less than 5 weeks corrected age
- Weigh less than 4.5 lbs
- Have asthma or a history of breathing problems (bronchospasm)
- Have certain heart conditions (such as slow heart rate, heart block, or heart failure)
- Have very low blood pressure
- Have high blood pressure caused by a tumor on the adrenal gland, called “pheochromocytoma”
- Are allergic to propranolol or any of the ingredients in HEMANGEOL

IMPORTANT SAFETY INFORMATION

HEMANGEOL may cause serious side effects, including:

Low blood sugar (hypoglycemia), which can be serious and may lead to seizures, loss of consciousness, or even death. This is more likely if your child is not eating well, is vomiting, or is sick. Always give HEMANGEOL during or right after feeding. Do not give a dose if your child is not eating. Signs of low blood sugar may include pale skin, sweating, irritability, unusual sleepiness, or seizures.

Bradycardia and hypotension. HEMANGEOL may slow your child’s heart rate or lower their blood pressure. Call your healthcare provider if your child seems unusually tired, dizzy, faints, or has pale or cold skin.

Bronchospasm. HEMANGEOL can cause breathing problems or make them worse. Get medical help right away if your child has wheezing or trouble breathing.

Cardiac failure. In certain patients with preexisting heart conditions, HEMANGEOL can worsen the heart’s ability to pump blood.

Increased risk of stroke. HEMANGEOL may increase the risk of stroke in children with certain blood vessel conditions (such as PHACE syndrome). Your healthcare provider may check for these conditions, especially in infants with large facial hemangiomas, before starting treatment.

Hypersensitivity. HEMANGEOL may make severe allergic reactions worse and may make it harder to treat these reactions with epinephrine (a medicine used in emergencies).

What are the most common side effects of HEMANGEOL?

The most common side effects include trouble sleeping, respiratory infections (such as colds or bronchitis), diarrhea, and vomiting.

Drug interactions

Tell your healthcare provider about all medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect how HEMANGEOL works or increase the risk of side effects, including medicines that affect how the body processes propranolol or increase the risk of low blood sugar (such as corticosteroids).

You are encouraged to report negative side effects of prescription drugs by contacting Eton Pharmaceuticals, Inc. at 1-855-224-0233 or the U.S. Food and Drug Administration (FDA) at https://www.fda.gov/safety/medwatch or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information for more information.

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Not an actual patient.

When it comes to IH, early action matters

- HEMANGEOL® is the **first and only FDA-approved treatment** for proliferating IH requiring systemic treatment
- **Specifically designed for pediatric patients*** — alcohol-free, no generic version or approved therapeutic equivalent
- **Clear or nearly clear results** in many babies **by 24 weeks**
- **Visible improvement** in most babies **by 5 weeks**
- **Trusted for over 12 years** to help treat IH



$0 copay
for eligible patients†

Visit HEMANGEOL.com to learn more.

*Do not give HEMANGEOL® to your child if they are less than 5 weeks old. If your child was born early, use their corrected age.

†Commercially eligible patients can pay $0 per month. Restrictions, limitations, and/or eligibility requirements may apply.

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eton PHARMACEUTICALS

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