



Hemangeol[®]

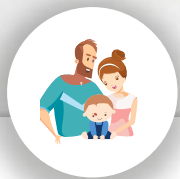
(propranolol hydrochloride)
oral solution **4.28 mg/mL**

Propranolol oral solution for proliferating hemangioma that requires systemic therapy

CAREGIVER GUIDE



Pierre Fabre
Pharmaceuticals, Inc.



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Your baby’s doctor has prescribed Hemangeol® (propranolol hydrochloride), an oral solution indicated in the treatment of proliferating infantile hemangioma requiring systemic therapy.

Before starting Hemangeol treatment, please read the Medication Guide provided in the Hemangeol package. It is important to share this information with everyone involved in the care of your baby.

As with many drugs, Hemangeol may cause side effects. This brochure provides important information on how to recognize and to manage the following risks associated with Hemangeol treatment.

- Low blood sugar (Hypoglycemia)
- Breathing difficulties (Bronchospasm)

These risks should be managed for the entire duration of treatment with Hemangeol, including any retreatment.

Administer Hemangeol exactly as prescribed with a feeding or immediately after a feeding. Do not try to make up for a missed dose.

Please see Important Safety Information on page 17 and accompanying Full Prescribing Information including Medication Guide.

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What is Hemangeol[®] ?

Hemangeol[®] (propranolol hydrochloride) is a prescription medicine used to treat proliferating infantile hemangioma that requires treatment with a medicine that spreads throughout the body.

Hemangeol has been developed and formulated as an oral solution, suitable specifically for infants. It contains no alcohol, sugar or parabens.

Hemangeol comes in a tasty strawberry-vanilla flavor. If needed, it can be added in a small amount of milk or fruit juice in the baby's bottle.

WHEN SHOULD A BABY START HEMANGEOL ?

In clinical trials, the age of babies starting the treatment was between 5 weeks and 5 months. Your doctor will determine what is the best age for your baby to start treatment.

HOW LONG DOES A BABY NEED TO TAKE HEMANGEOL ?

Treatment with Hemangeol is recommended for six months. In the pivotal clinical trial, Hemangeol was taken for six months, with about 60% of patients achieving complete or nearly complete resolution of their hemangioma (compared to 4% of patients taking placebo). About 10% of the infants required re-treatment due to the IH coming back. Your doctor will decide how long your baby should be on Hemangeol.¹



The First and Only FDA APPROVED product for infantile hemangioma.

Please see Important Safety Information on page 17 and accompanying Full Prescribing Information including Medication Guide.

1- Hemangeol product information. [Full Prescribing Information]. Parsippany, NJ: Pierre Fabre Pharmaceuticals, Inc; 2021
2- Storch CH & Hoeger PH. Br J Derm 2010;163:269-274.

HOW DOES HEMANGEOL WORK ?

It is not known how Hemangeol works. However, it is thought that Hemangeol works by narrowing those blood vessels that are already formed, preventing new ones from growing, and/or leading to the destruction of unwanted hemangioma cells.²



Treatment was fully successful in 60% of patients.¹

WAS HEMANGEOL TESTED IN A CLINICAL TRIAL ?

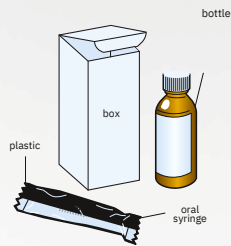
Hemangeol was studied in a primary clinical trial in 460 babies with proliferating (growing) Infantile Hemangiomas (excluding life-threatening IH, function-threatening IH, and ulcerated IH with pain and lack of response to simple wound care measures). In this study, 60% of babies on Hemangeol had their IH lesion "completely or nearly completely resolved" by six months of therapy versus only 4% of babies given placebo (no treatment). 88 % of patients on Hemangeol showed improvement after 5 weeks of treatment.*

Less than 2% of the babies who were given Hemangeol had to stop treatment due to adverse experiences. The most common side effects included sleep problems, worsening respiratory tract infections, diarrhea, and vomiting.¹

*Based on independent-investigator assessment of telangiectasis, color, textural change and distortion of anatomical landmarks or skin contours compared to baseline.

Instructions for use

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

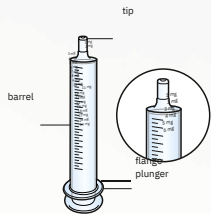


1 - REMOVE THE ITEMS FROM THE BOX

- 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.



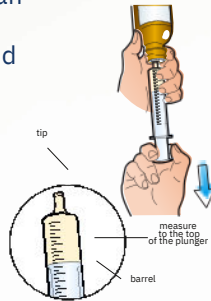
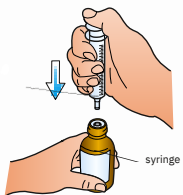
3 - OPEN THE BOTTLE

- 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 baby'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.

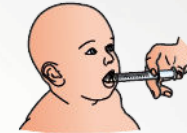
7 - REMOVE THE SYRINGE

- Turn bottle upright again and place it in 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.

8 - CLOSE THE BOTTLE

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

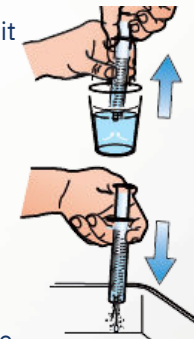
9 - GIVE HEMANEOL® TO YOUR BABY



Slowly squirt HEMANGEOL into your baby's mouth after placing the oral dosing syringe against the inside of the cheek.

- Keep your baby 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 baby in a baby's bottle. If your baby spits up a dose or if you are not sure your baby got all of the medicine, do not give another dose. Wait until the next scheduled dose.

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.



Low blood sugar level (Hypoglycemia)

Hemangeol can cause hypoglycemia, also known as low blood sugar and may make it more difficult to recognize the signs and symptoms of low blood sugar in your child.

This risk is increased:

- during a fasting period (e.g., poor oral food intake, vomiting, teething)
- when glucose demands are increased (e.g., cold, stress, infections).

Hypoglycemia can also occur when too much Hemangeol is given (overdosage).

WHAT ARE THE SIGNS OF HYPOGLYCEMIA ?

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.

Hemangeol can mask the signs and symptoms of hypoglycemia, especially particularly fast heart rate, palpitations and sweating. Certain signs and symptoms of hypoglycemia can also be confused with potential side effects of propranolol: pale, blue or purple skin color, arms or legs feel cold, or fainting due to slow heart rate (bradycardia) or low blood pressure (hypotension).

If your child shows signs or symptoms of low blood sugar, stop the treatment and call your healthcare provider immediately or go to the emergency room. If the child is conscious, give him/her a drink of liquid containing sugar.

WHAT TO DO IF HYPOGLYCEMIA IS SUSPECTED ?

If your baby has any sign of hypoglycemia while taking Hemangeol:



Stop treatment,



• If your baby is conscious, give him/her a drink of sugar liquid



• Call your healthcare provider immediately or go to the emergency room



STEPS TO REDUCE THE RISK OF HYPOGLYCEMIA

The risk of hypoglycemia remains equally prominent during the whole period of treatment, whatever the age your baby attains. This risk can also occur when resuming the treatment.

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, for example, due to an illness or vomiting, do not give Hemangeol until your child is taking feedings normally again.

Please see Important Safety Information on page 17 and accompanying Full Prescribing Information including Medication Guide.



Low blood sugar level (Hypoglycemia)

Feeding recommendations during treatment



- Give Hemangeol during or straight after a feeding (breast milk, formula milk or solids).



- The same person should give both your baby's feeding and Hemangeol. If you cannot avoid different people being involved, it is essential that you are in good communication with everyone else involved.



- Skip the dose if your baby has decreased intake or is vomiting. Do not give Hemangeol to your baby until he or she has been sufficiently fed again without vomiting afterwards.



- If your child shows signs or symptoms of low blood sugar, stop the treatment and call your healthcare provider immediately or go to the emergency room. If the child is conscious, give him/her a drink of liquid containing sugar.

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Administer Hemangeol dose exactly as prescribed

- Never change the dose by yourself.
- If you forget to give your baby a dose of Hemangeol, do not give another dose. Just wait until the next scheduled dose.
- If you give too much Hemangeol to your baby, contact your healthcare provider immediately.

Steps to reduce risk of hypoglycemia overnight

- Give the **first dose in the morning and the last dose no later than in late afternoon**, always with meal. Hemangeol is given 2 times each day, at least 9 hours apart.

If you have any questions about Hemangeol or any other medication your baby is taking, you should speak to your physician.



Breathing problems (Bronchospasm)

Hemangeol can cause the tightening of the body's air passages leading to difficulty in breathing (like in asthma), including exacerbation of lower respiratory tract infections. Hemangeol should not be given to patients with asthma or a history of bronchospasm.

WHAT ARE THE SIGNS OF BREATHING PROBLEMS ?

Signs of breathing difficulties include:

- Cough,
- Quick or difficult breathing or wheezing with or without bluish skin discoloration.

WHAT TO DO WHEN BREATHING PROBLEMS ARE SUSPECTED



Call your healthcare provider or go to the nearest emergency room if your child has breathing problems or wheezing during treatment with Hemangeol.

Hemangeol treatment may be restarted, according to the doctor's recommendations, when your baby has fully recovered.

ADVERSE REACTIONS

The most common side effects include: sleep problems, worsening respiratory tract infections, diarrhea, and vomiting.

Please see Important Safety Information on page 17 and accompanying Full Prescribing Information including Medication Guide.

In Summary



LOW BLOOD SUGAR (HYPOGLYCEMIA)

- Give Hemangeol **during or straight after a feeding**.
- The same person should give both your baby's feeding and Hemangeol. If you cannot avoid different people being involved, it is essential that you are in good communication with everyone else involved.
- **Skip the dose if your baby has decreased intake or is vomiting. Do not give Hemangeol to your baby until he or she has been sufficiently fed again without vomiting afterwards.**
- If your child shows **signs or symptoms of low blood sugar, stop treatment and call your healthcare provider immediately or go to the emergency room.** If the child is conscious, give him/her a drink of liquid containing sugar.

SIGNS	ACTION
<p>Pale, blue or purple skin color</p> <p>Sweating</p> <p>Irritability</p> <p>Crying for no apparent reasons</p> <p>Irregular or fast heartbeat,</p> <p>Poor feeding</p> <p>Low body temperature</p> <p>Unusual sleepiness</p> <p>Seizures</p> <p>Breathing stops periods of time</p> <p>Loss of consciousness</p>	<ol style="list-style-type: none"> 1. Stop treatment 2. Call your healthcare provider immediately or go to the emergency room. 3. If the child is conscious, give him/her a drink of liquid containing sugar.

Please see Important Safety Information on page 17 and accompanying Full Prescribing Information including the Medication Guide

BREATHING PROBLEMS (BRONCHOSPASM)

SIGNS	ACTION
<p>Cough</p> <p>Quick or difficult breathing</p> <p>Wheezing</p> <p>Bronchitis</p>	<p>Hemangeol can cause spasms of your child's airway. Call your doctor or go to the nearest hospital emergency room if your child has breathing problems or wheezing during treatment with HEMANGEOL.</p>

WARNINGS AND PRECAUTIONS

HEMANGEOL can cause 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. 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.

Hemangeol can cause other serious side effects including:

- 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.



USING HEMANGEOL



HOW IS THE DOSE OF HEMANGEOL DETERMINED ?

The amount of Hemangeol that you give to your baby is based on your baby's weight and is therefore very specific to your baby. You will be instructed to give your baby a specific amount of Hemangeol solution, measured in milliliters (mL), using the oral syringe provided, **two times a day, once in the morning and once in late afternoon.** You should leave **at least 9 hours between the two doses during the day.**

Your baby's dose will be started low and will be slowly increased every week over 3 weeks until the maintenance dose is reached.

Any increase in dose must only be decided by your physician at scheduled visits that are arranged. At these visits, you will be told the new amount of Hemangeol to give your baby.

As your baby is growing rapidly and is gaining weight, your doctor may change the dose of Hemangeol as your child's weight changes.



PRESCRIBED EFFECTIVE DOSE IN ML

YOU MUST GIVE YOUR BABY THE EXACT AMOUNT OF HEMANGEOL THAT HAS BEEN PRESCRIBED. NEVER CHANGE THE AMOUNT YOU ARE GIVING YOUR BABY BY YOURSELF.



WHAT SHOULD I DO IF I FORGET TO GIVE HEMANGEOL TO MY BABY?

If you forget to give your baby a dose of Hemangeol, do not give another dose - just wait until the next scheduled dose.

WHAT SHOULD I DO IF I GIVE TOO MUCH HEMANGEOL TO MY BABY?

If you give too much Hemangeol to your baby, contact your physician immediately.

NEVER TRY TO MAKE UP FOR ANY DOSES THAT WERE MISSED.

WHAT SHOULD I DO IF MY BABY REFUSES TO TAKE HEMANGEOL ?

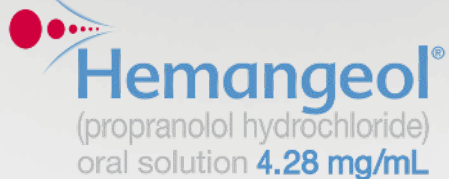
If your baby refuses to take Hemangeol, you can mix it with a small amount of baby milk (breast milk or formula milk) or fruit juice and give it in a baby's bottle.

CONTRAINDICATIONS

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"

Please see Important Safety Information on page 17 and accompanying Full Prescribing Information including Medication Guide.



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

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

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 the doctor about all medicines 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.



Pierre Fabre
Pharmaceuticals, Inc.