

Facts you should know about
infantile hemangioma

GUIDANCE **FOR** PARENTS



Dramatization of infantile hemangioma.



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DERMATOLOGIE

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Hemangeol™ is a prescription medicine used to treat proliferating infantile hemangioma that requires treatment with a medicine that spreads throughout the body.

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 1/2 pounds
- is allergic to propranolol or any of the other ingredients in Hemangeol™
- has asthma or a history of breathing problems

What is infantile hemangioma?

Infantile hemangiomas are benign tumors formed from the overgrowth of blood vessels, on or under the skin.¹ Infantile hemangioma (also known as IH) is sometimes called a 'strawberry mark' due to its color and surface appearance.²

Infantile hemangiomas can occur anywhere on the body, but are often on the face and neck.² They may form a nodule or have a plaque-like appearance.²

Why does my baby have infantile hemangioma?

The causes of infantile hemangioma are not well understood. However, we know certain babies are at higher risk of infantile hemangioma. These include babies with lower birth weight, females, caucasians, and premature babies.³

It is important to know that you did nothing wrong and it is not your fault if your baby has infantile hemangioma.



Dramatization of infantile hemangioma.

Is infantile hemangioma contagious?

Infantile hemangioma is not contagious so your baby can continue to be around other babies and of course, hugged by all members of your family.

IMPORTANT SAFETY INFORMATION (Please read more on pages 16-17)

- 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".



Is infantile hemangioma a serious condition?

In some severe cases, hemangiomas can interfere with an important function:⁴

- On the eyes, it can affect your child's vision, especially because eye development is crucial at an early age.
- On the nose, it can affect your child's breathing.
- On the mouth, it can affect your child's food intake.

Some infantile hemangiomas are at high risk of bleeding, which can lead to anemia, blood transfusion, and/or infection. Infantile hemangiomas that are bleeding can also be extremely painful for your baby.



Although most infantile hemangiomas can resolve on their own by the time your child is 7 to 9 years old, permanent disfigurement is a serious consequence that you should be aware of:

- 1 out of 3 facial hemangiomas will result in disfigurement from permanent soft tissue distortion, which can be truly life-altering.
- 69% of hemangiomas can leave permanent residual lesions (i.e. scars, extra skin, extra fatty tissue, etc).^{4,5}

Infantile hemangiomas grow quickly, appearing shortly after birth.² By the time your baby is 3 months old, the hemangioma growth will be 80% complete. By the time your baby is 5 months old, the hemangioma will be at full size.⁶



Actual images of infantile hemangioma

Ask your doctor how serious your baby's infantile hemangioma is.

NOW IS THE TIME TO ASK YOUR DOCTOR HOW SERIOUS YOUR BABY'S IH IS





Dramatization of infantile hemangioma.



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

What is Hemangeol™?

The first and only

FDA

APPROVED
product for infantile
hemangioma

Hemangeol™ is a prescription medicine used to treat proliferating (growing) 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.

It comes in a tasty strawberry-vanilla flavor and can be added to small amounts of milk or juice.

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.⁸



Dramatization of infantile hemangioma.

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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 1/2 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 is taking, or all the medicines you are taking if you are breastfeeding.

Hemangeol™ can cause serious side effects, including:

Low blood sugar (hypoglycemia), especially if your child is not taking feedings, or is vomiting. **To help reduce the risk of low blood sugar with Hemangeol™**, give Hemangeol™ during or shortly after feeding your child. 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. Tell your doctor if your child has a poor appetite.

If your child has any of the signs or symptoms of low blood sugar during treatment with Hemangeol™, stop giving your child Hemangeol™ and call your doctor or go to the nearest emergency room right away.

Treatment was fully successful in

60%
of patients.

Was Hemangeol™ tested in a clinical trial?

Hemangeol™ was studied in a primary clinical trial in 460 babies with proliferating (growing) 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 the babies treated with Hemangeol™ showed improvement after 5 weeks.⁷

Less than 2% of the babies who were given Hemangeol™ had to stop treatment due to adverse experiences.



Dramatization of infantile hemangioma.

Actual Hemangeol™ patients from the clinical trial



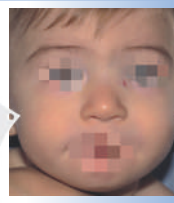
Before treatment



After 6 months of Hemangeol™



Before treatment



After 6 months of Hemangeol™

**ASK YOUR DOCTOR
IF YOUR BABY CAN
BENEFIT FROM
HEMANGEOL™.**



A second uncontrolled study in 23 patients with proliferating IH included function-threatening IH, IH in certain anatomic locations that often leave permanent scars or deformity, large facial IH, smaller IH in exposed areas, severe ulcerated IH, and pedunculated IH. Target lesions resolved in 36% of patients by 3 months.

Ask your doctor if your baby can benefit from Hemangeol™.

What age should my child 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.

For how long will my baby need to take Hemangeol™?

In the clinical trial, Hemangeol™ was taken for six months. 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™.⁷

SELECTED SAFETY INFORMATION (Please read more about side effects on pages 16-17)

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 may report side effects to FDA at 1-800-FDA-1088.

Hemangeol™ can cause serious side effects, including:

- **New or worsening slow heart rate (bradycardia) or low blood pressure (hypotension).**
- **Breathing problems or wheezing.**
- **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.



How much Hemangeol™ do I give?

Your doctor will determine the amount of Hemangeol™ your baby needs based on their weight. This amount may change over the course of treatment, as your baby grows. Safety and effectiveness for infantile hemangioma have not been established in pediatric patients greater than 1 year of age. Your doctor will advise you on any dosing adjustments and the need for follow-up appointments.

How do I give Hemangeol™ to my child?

Hemangeol™ comes with a specifically designed oral dosing syringe and bottle adapter for your convenience. Follow the detailed instructions for use that come with Hemangeol™ about the correct way to prepare and give a dose of Hemangeol™. Give Hemangeol™ to your child exactly as your doctor tells you.

Your doctor may change the dose until it is right for your child, and as your child's weight changes.

Always give Hemangeol™ with a feeding or right away after a feeding. Hemangeol™ is given 2 times a day, at least 9 hours apart.

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.

Your doctor and you will know what is best for your baby.

REMEMBER YOUR DOCTOR IS THERE TO HELP:
ASK HIS OR HER ADVICE

SELECTED SAFETY INFORMATION

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 and if your child is not feeding due to an illness or vomiting.



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Where do I get Hemangeol™?

Hemangeol™ is a prescription product that must be ordered by your doctor through Hemangeol™ Patient Access, a mail order pharmacy. After receiving a prescription from your doctor, Hemangeol™ Patient Access customer service will contact you to arrange a delivery.

If for some reason, you need to get Hemangeol™ from a pharmacy, ask your doctor and arrangements can be made through Hemangeol™ Patient Access.

How much can I expect to pay for Hemangeol™?

The cost of Hemangeol™ depends on your family's individual insurance plan. In general, Hemangeol™ is covered by most insurance plans so your child can benefit today. Pierre Fabre also offers patient assistance to those in need.

SELECTED SAFETY INFORMATION (Please read more on pages 16-17)

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. If your child has any of these signs or symptoms, stop giving your child Hemangeol™ and call your doctor or go to the nearest emergency room right away.

What should I know when my baby has been prescribed Hemangeol™?

What can I expect when my doctor initiates treatment or changes dose of Hemangeol™?

To ensure your baby can tolerate Hemangeol™, the doctor will typically check to see if your baby experiences slowing of the heart rate (bradycardia) or low blood pressure (hypotension) up to 2 hours when Hemangeol™ is first started or the dose is increased.

How do I recognize and help reduce the risk of low blood sugar (hypoglycemia)?

Hemangeol™ can cause serious adverse side effects like low blood sugar, but there are steps that you can take to reduce the risk. Hemangeol™ should be administered during or immediately after feeding.



Dramatization of infantile hemangioma.

Hemangeol™ may make it more difficult to recognize the signs and symptoms of low blood sugar in your child. Feed your child regularly during treatment and tell your doctor if your child has a poor appetite.

If necessary, you can add Hemangeol™ to a small amount of milk or juice. If your child is not feeding due to an illness or vomiting, do not give Hemangeol™ until your child is taking feedings normally again.

It is important to be aware of the signs of low blood sugar which include: paleness, tiredness, sweating, shakiness, palpitations (noticeable heartbeats, usually fast or irregular), anxiety, hunger, difficulty waking up, sleeping more than normal, difficulty in getting a response, poor feeding, decrease in temperature, convulsions (fits) and brief pauses in breathing.

If your baby shows any of these signs, contact your doctor or go to the nearest emergency room right away.

How do I know if my baby has a slow heart rate or low blood pressure?

The effects of Hemangeol™ may cause slow heart rate or low blood pressure. You should be aware of these serious possibilities. Signs of an abnormally slow heart rate or low blood pressure are tiredness, coldness to the touch, pale or bluish colored skin, or fainting. If your baby shows any of these signs, contact your doctor.

What do I do if my child has breathing problems or wheezing?

Hemangeol™ can cause spasms of your child's airways. If your child experiences breathing problems or wheezing, call your doctor or go to an emergency room right away.

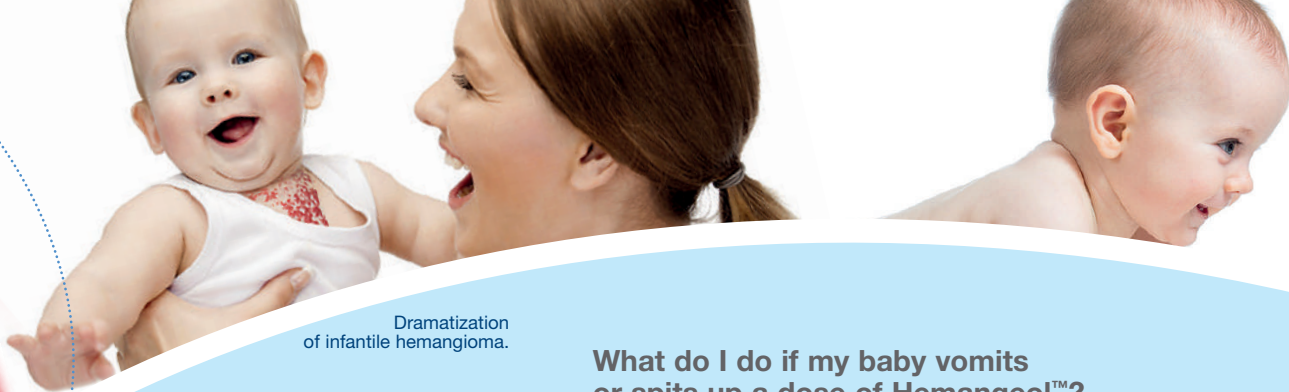


Common questions

What should I do if my baby is sick?

If your child is not eating because of illness, is vomiting, or has diarrhea, you should not give Hemangeol™ until your child's feeding is back to normal. Once their appetite has returned, and vomiting or diarrhea has passed, you can give the next planned dose after a meal.

It is important to not try and make up for missed doses of Hemangeol™. This could lead to overdosing, which can be potentially dangerous.



Dramatization
of infantile hemangioma.

What do I do if my baby vomits or spits up a dose of Hemangeol™?

If your child vomits or spits up a dose or if you are uncertain whether they really got the whole Hemangeol™ dose, don't worry. There is no need to try and make up the dose; just wait until the next scheduled dose.

What do I do if my baby has missed a dose of Hemangeol™?

Sometimes things don't go as planned and a dose of Hemangeol™ is forgotten. Do not make up the dose and wait until the next scheduled dose.



Dramatization of infantile hemangioma.



Are there patient support groups that can provide me support or more information?

NOVA (National Organization of Vascular Anomalies)

The National Organization of Vascular Anomalies is a patient support, advocacy and educational agency for those affected by hemangioma, vascular malformation, rare benign tumors and many related syndromes.

<http://www.novanews.org/>

VBF (Vascular Birthmarks Foundation)

An international charitable organization that networks families affected by a vascular birthmark, tumor, or syndrome to the appropriate medical professionals for evaluation and/or treatment, provides informational resources as well as sponsors physician education, mobilizes medical missions trips, and supports research and programs that promote acceptance for individuals with birthmarks.

<http://www.birthmark.org/>

What should I do if my baby refuses to take Hemangeol™?

If your baby refuses to take Hemangeol™ through the oral dosing syringe, Hemangeol™ can be mixed with a small amount of fruit juice or milk (breast or formula) and given in a bottle. Remember to use any diluted Hemangeol™ within 2 hours of mixing.

What should I do if I lose the dosing syringe?

The oral dosing syringe that comes in the Hemangeol™ box is specifically designed to measure Hemangeol™. Therefore, if you've lost or misplaced the syringe, contact Hemangeol™ Patient Access at 1-855-618-4950 for another one, before giving your baby the next Hemangeol™ dose.

Hemangeol™ Patient Access is available 24 hours a day if you have any questions about Hemangeol™.


**HEMANGEOL™
PATIENT ACCESS
HAS A 24/7 HOTLINE
JUST FOR YOU**

**CONTACT:
1-855-618-4950**



**WHERE CAN I FIND
MORE INFORMATION
ABOUT HEMANGEOL™?**

www.hemangeol.com



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 1/2 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 is taking, or all the medicines you are taking if you are breastfeeding.

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 feeding 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.

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.

For more information about Hemangeol™, please talk to your doctor or visit: www.hemangeol.com

Please see accompanying Prescribing Information.



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

PATIENT ACCESS

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