MEDICATION GUIDE HEMANGEOL®
(hem-an je-ohl) (propranolol hydrochloride oral solution)

What is the most important information I should know about HEMANGEOL®?

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 for your child to recognize the signs and symptoms of low blood sugar in your child.
- Helps 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.
  • Keep a record of your child’s blood sugar levels.

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, 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 is HEMANGEOL®?

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

Who should not take HEMANGEOL®?

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. See the end of this Medication Guide for a list of ingredients in HEMANGEOL.
- has a history of breathing problems.
- has a heart problem, slow heart rate (less than 80 heart beats per minute), very low blood pressure, and severe sleep problems.
- has high blood pressure caused by a tumor on the adrenal gland, called “pheochromocytoma.”

What should I tell my doctor before giving my child HEMANGEOL®?

Before you start giving HEMANGEOL® to your child, tell your doctor about all of your child’s medical conditions.

Tell your doctor about all of the medicines that your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. HEMANGEOL and some medicines may interact with each other and cause serious side effects. Especially tell your doctor if your child takes a steroid medicine. Taking a steroid medicine during treatment with HEMANGEOL may increase your child’s risk of low blood sugar.

If you are breastfeeding your child, it is important to tell your doctor about all the medicines you take. Certain medicines may pass to your child through your breast milk and interact with HEMANGEOL. Your doctor should tell you if you should stop breastfeeding.

How should I give HEMANGEOL® to my child?

Follow the detailed Instructions for Use that come with HEMANGEOL® for information about the correct way to prepare and give a dose of HEMANGEOL. Always 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 after a feeding.
- HEMANGEOL® is given 2 times each day, at least 6 hours apart.
- Give HEMANGEOL® during or shortly after feeding your child.
- Give HEMANGEOL® to your child exactly as your doctor tells you. Wait until the next scheduled dose.

What are the possible side effects of HEMANGEOL®?

See “What is the most important information I should know about HEMANGEOL®?”

HEMANGEOL can cause serious side effects, including:

- New or worsening slow heart rate (bradycardia) or low blood pressure (hypotension). Call your doctor if your child has any of these symptoms: 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 a loss of your child’s airway. Call your doctor if your child has breathing problems or wheezing during treatment with HEMANGEOL.
- 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.
- The most common side effects include: slow 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.

How should I store HEMANGEOL®?

- Store HEMANGEOL at room temperature between 68 °F to 77 °F (20 °C to 25 °C). Do not freeze. Do not store in the refrigerator.
- Keep HEMANGEOL and all medicines out of the reach of children.

What are the ingredients in HEMANGEOL®?

Active ingredient:
propranolol hydrochloride

Inactive ingredients:
strawberry flavor, vanilla flavor, hydroxyethylcellulose, saccharin sodium, citric acid monohydrate, and water.

Manufactured for: Pierre Fabre Pharmaceuticals, Inc., Parsippany, NJ 07054

For more information, call 1-855-PFPHARM (737-4276)

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: June 2021