

MEDICATION GUIDE

HEMANGEOL[®] (he-man 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 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, for example, 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.

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 ½ 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 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”

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.

- 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 each 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.

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 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.
- **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: 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.

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 shake before use.
- Safely throw away any opened bottle of HEMANGEOL after 2 months, even if there is medicine left in the bottle.

Keep HEMANGEOL and all medicines out of the reach of children.

General information about the safe and effective use of HEMANGEOL.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or doctor for information about HEMANGEOL that is written for health professionals. Do not use HEMANGEOL for a condition for which it was not prescribed. Do not give HEMANGEOL to other people, even if they have the same symptoms your child has. It may harm them.

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
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