


Follow Up Sheet

כרטיס מעקב

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| 5 | <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Proof No.</th> <th style="width: 20%;">Languages</th> <th style="width: 20%;">Date Modified</th> <th style="width: 20%;">Modified by</th> </tr> </thead> <tbody> <tr><td>1</td><td>Eng</td><td>10.11.20</td><td>Karina</td></tr> <tr><td>2</td><td>Eng</td><td>21.12.20</td><td>Karina</td></tr> <tr><td>3</td><td>Eng</td><td>12.01.21</td><td>Karina</td></tr> <tr><td>4</td><td>Eng</td><td>25.01.21</td><td>Karina</td></tr> <tr><td>5</td><td>Eng</td><td>18.03.21</td><td>Karina</td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table> | | Proof No. | Languages | Date Modified | Modified by | 1 | Eng | 10.11.20 | Karina | 2 | Eng | 21.12.20 | Karina | 3 | Eng | 12.01.21 | Karina | 4 | Eng | 25.01.21 | Karina | 5 | Eng | 18.03.21 | Karina | | | | | | | | | | | | | Heb = Hebrew Eng = English Arab = Arabic Rus = Russian |
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Hemangiol[®]

PROPRANOLOL

3.75 mg/mL, oral solution

**Propranolol oral solution for the
treatment of infantile haemangioma**

CARER GUIDE



Perrigo

Pierre Fabre
DERMATOLOGIE



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Your child's doctor has prescribed your child Hemangiol® an oral solution specifically developed for the treatment of infantile haemangioma in infants who require oral treatment.

Before starting Hemangiol® treatment, carefully read the patient leaflet provided in the Hemangiol® box. It is important to share this information with everyone involved in the care of your child.

As many drugs, Hemangiol® may cause unwanted side effects.

This brochure provides important information about the following risks associated with the treatment with Hemangiol®.

- Low blood sugar/Hypoglycemia
- Breathing difficulties/bronchospasm

These risks should be managed during the whole duration of the treatment with Hemangiol, whatever the age of the child has attained and even when resuming the treatment after eventual treatment discontinuation.

Administer this medicine exactly as prescribed; do not alter the dose of Hemangiol® yourself. Never try to make up for any doses that are missed.

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Low blood sugar level or Hypoglycemia

Babies are susceptible to hypoglycemia, also known as low blood sugar level, especially:

- When glucose demands are increased (cold, stress, infections/increased work of breathing)
- During fasting period (poor oral food intake, concomitant infection, teething).

At normal doses, **Hemangiol can aggravate hypoglycemia and /or mask some warning signs related to hypoglycaemia**, particularly if the baby is fasting or eating not enough food or vomiting. The same can occur if overdosing Hemangiol.

HOW SHOULD I RECOGNISE THE SIGNS OF HYPOGLYCEMIA?

The warning signs of hypoglycemia are pallor, sweating, tiredness, shaking, palpitations (noticeable heartbeats, usually fast or irregular), anxiety, hunger, difficulty waking up.

When not appropriately treated, hypoglycemia may worsen and the following signs may occur:

- Sleeping more than normal,
- Difficulty in getting a response,
- Poor feeding (decreased appetite),
- Decrease in body temperature,
- Convulsions,
- Brief pauses in breathing,
- Loss of consciousness.

Hemangiol® may mask some of the signs of hypoglycemia and hence it would be difficult to recognize them. In addition, the signs of hypoglycemia may be similar to some of the side effects of propranolol itself:

- Problems with sleeping and waking up due to central nervous system effects,
- Pallor, fatigue and faintness due to decreased blood pressure (hypotension).

If a side effect occurs, if one of the side effects aggravates or if your child experiences a side effect which was not mentioned in the leaflet, you should contact the doctor.



Low blood sugar level or Hypoglycemia

WHAT SHOULD I DO IN CASE OF SUSPICION OF HYPOGLYCEMIA?



If your child has any sign of hypoglycaemia while taking Hemangiol®:



- **Stop treatment,**



- If your child is conscious and can swallow, give oral sugary liquid,



- If your child is not conscious or cannot swallow, go directly to hospital,



- If symptoms persist, call a doctor right away or go directly to hospital.

HOW TO AVOID RISKS OF HYPOGLYCEMIA?

The risk of hypoglycemia remains equally prominent during the whole period of treatment, whatever the age your child attains. This risk can also occur when resuming the treatment. **It is important to respect the dosing recommendations by administering Hemangiol during or right after feeding to avoid the risk of hypoglycaemia it is also important to avoid giving dose before sleep time.** *(See complete instructions for use on page 14)*



Low blood sugar level or Hypoglycemia

How your child must be fed during treatment?



- Give Hemangiol® **during or straight after a feed** (breast milk, formula milk or solids) to avoid long periods of time without food and do not give the last dose before sleep time.



- In order to avoid mistakes in the administration of Hemangiol®, it is recommended that the same person who feeds your child, will also give him Hemangiol®. If there is no such possibility, it is essential to ensure good communication with everyone else involved.



- It is recommended to skip the dose if your child is not eating correctly, is vomiting, or develops another illness (*e.g. diarrhea or infection such as gastro-enteritis*). Do not give Hemangiol® to your child until he has been correctly fed again without vomiting afterwards.



Low blood sugar level or Hypoglycemia

You must give your child the exact dose of Hemangiol® that has been prescribed:

- Never change the dose by yourself.
- If you forget to give your child a dose of Hemangiol®, do not give another dose just wait until the next scheduled dose.
- If you give too much Hemangiol® to your child, contact a doctor immediately.

How to prevent hypoglycemia during sleeping?

- Give **the first dose in the morning and the last dose no later than in late afternoon**, always with meal. Do not give Hemangiol® just before sleep time.

If you have any questions about Hemangiol® you should speak to the doctor.





Breathing difficulties or bronchospasm

Hemangiol® can cause the tightening of the body's air passages leading to difficulty in breathing (like in asthma), particularly related to bronchial infections during winter.

HOW CAN I RECOGNIZE IF MY CHILD HAS BREATHING DIFFICULTIES?

Signs of breathing difficulties include:

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



Breathing difficulties or bronchospasm

**WHAT SHOULD I DO AND
WHEN SHOULD I GO TO THE DOCTOR?**



**If your child has difficulties in breathing or wheezing,
stop treatment and contact a doctor immediately.**

Hemangiol[®] treatment may be restarted, according to the doctor's recommendations, when your child has fully recovered.

In Summary



LOW BLOOD SUGAR/HYPOGLYCEMIA

- Give Hemangiol® during or straight after a feed and do not give the last dose just before sleep time.
- The same person should give both your child's feed and Hemangiol® to avoid the mistake in administration. In case this is not possible, at least, a good communication with everyone else involved should be ensured.
- It is recommended to skip the dose if your child is not eating correctly, is vomiting, or develops another illness (e.g. diarrhea or infection such as gastro-enteritis). Do not give Hemangiol® to your child until he has been correctly fed again without vomiting afterwards.
- Stop treatment and contact a doctor if your child has cold-like symptoms associated with difficulty in breathing and/or wheezing.

| SIGNS | ACTION |
|---|--|
| Early signs (can be masked) | <ol style="list-style-type: none"> 1. Stop treatment 2. Give a drink of sugary liquid if your child is conscious and can swallow 3. If symptoms persist contact a doctor immediately or go straight to hospital |
| Paleness | |
| Sweating | |
| Tiredness | |
| Shakiness | |
| Palpitations (noticeable heartbeats, usually fast or irregular) | |
| Anxiety | |
| Hunger | |
| Difficulty waking up | |
| Signs of aggravation | |
| Sleeping more than normal | |
| Difficulty in getting a response (apathy) | |
| Poor feeding (decreased appetite) | |
| Decrease in temperature | |
| Emergency | |
| Convulsions | |
| Brief pauses in breathing | |
| Loss of consciousness | |

In Summary



BREATHING DIFFICULTIES/BRONCHOSPASM

| SIGNS | ACTION |
|--------------------------------------|--|
| Cough | <ol style="list-style-type: none">1. Stop treatment2. Contact a doctor immediately3. Hemangiol[®] may be restarted, according to the doctor's recommendations, when your child has fully recovered. |
| Quick or difficult breathing | |
| Wheezing | |
| With or without bluish-coloured skin | |

Using Hemangiol®

HOW HAS THE DOCTOR DECIDED WHAT DOSE OF HEMANGIOL® TO GIVE MY CHILD?

The amount of Hemangiol® that you give to your child is based on your child's weight and is therefore very specific to your child. You will be instructed to give your child a specific amount of Hemangiol® solution, measured in milligrams (mg) of active ingredient, 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.

Do not use other syringe except the one provided in the box of Hemangiol®.

Your child's dose will be started low and will be slowly increased every week over 3 weeks until the final effective dose is attained. Any increase in dose must only be decided by the doctor at the weekly visits that are arranged. At these visits, you will be told the new amount of Hemangiol® to give your child.

As your child is growing rapidly and is gaining weight, it is then necessary to adjust the amount of Hemangiol® that your child receives, according to your child's weight. He/she will need to regularly receive a larger amount of Hemangiol® to have the same effect. **This adjustment will be done by the doctor at least every month.**

PRESCRIBED EFFECTIVE DOSE IN MG

YOU MUST GIVE YOUR CHILD THE EXACT AMOUNT of Hemangiol® that has been prescribed. Never change the amount you are giving your child by yourself.

WHAT SHOULD I DO IF I FORGET TO GIVE HEMANGIOL® TO MY CHILD?

If you forget to give your child a dose of Hemangiol®, **do not give another dose** - just wait until the next scheduled dose.

Using Hemangiol®

WHAT SHOULD I DO IF I GIVE TOO MUCH HEMANGIOL® TO MY CHILD?

If you give too much Hemangiol® to your child, **contact the doctor immediately**.

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

WHAT SHOULD I DO IF MY CHILD REFUSES TO TAKE THE HEMANGIOL® MEDICATION?

If your child refuses to take Hemangiol®, you can **mix it with a small volume of baby milk** (breast milk or formula milk) or apple/orange juice suitable for your child's age, as follows, and give it in a baby's bottle:

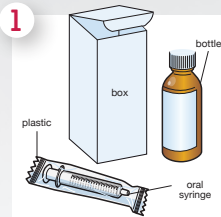
For children up to 5 kg mix Hemangiol® with 1 teaspoon (about 5 mL) of baby milk.

For children over 5 kg mix Hemangiol® with 1 tablespoon (about 15 mL) of baby milk or apple/orange juice suitable for your child's age. The mixture should be used within 2 hours. Do not mix Hemangiol® with a full bottle of milk or fruit juice.

MIX IT WITH A SMALL VOLUME OF BABY MILK OR FRUIT JUICE



Instructions for use

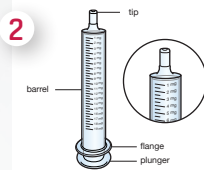


1 - REMOVE THE ITEMS FROM THE BOX

The carton contains the following items that you will need to administer the medicine:

- A glass bottle containing 120 ml Hemangiol® oral solution
- The oral syringe graduated in mg provided with this medicine.

Remove the bottle and oral syringe from the box and remove the syringe from the plastic bag.



2 - CHECK THE DOSE

Check the Hemangiol® dose in milligrams (mg) as prescribed for your child by the doctor. Locate this number on the oral syringe.

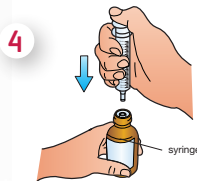


3 - OPEN THE BOTTLE

The bottle comes with a child-proof cap.

Here is how to open it: push down the plastic cap while turning the cap counterclockwise (to the left).

Do not shake the bottle before use.



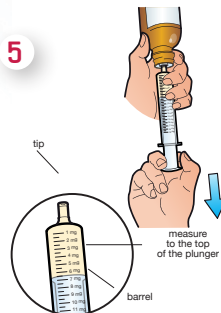
4 - INSERT THE SYRINGE

Insert tip of the oral syringe into the upright bottle and push the plunger all the way down.

Do not remove the syringe adapter from the neck of the bottle.

Only use the oral syringe that is supplied with the medicine to measure and administer the dose.

Do not use a spoon or any other dispensing device (also not other syringe).



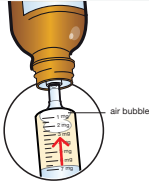
5 - REMOVE THE DOSE

With the oral syringe in place, turn the bottle upside down.

Pull the plunger of the syringe up to the number of mg you need.

Instructions for use

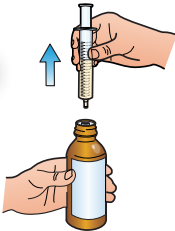
6



6 - CHECK FOR AIR BUBBLES

If you see air bubbles in the syringe, hold the syringe upright, push the plunger upwards just far enough to completely push out any large air bubbles and then readjust to the dose prescribed by your doctor.

7



7 - REMOVE THE SYRINGE

Turn bottle upright and remove the entire syringe from the bottle. Do not push the plunger in during this step.

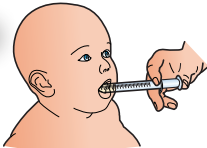
8



8 - CLOSE THE BOTTLE

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

9



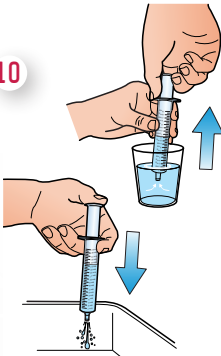
9 - GIVE HEMANGIOL® TO YOUR CHILD

Insert the syringe into your baby's mouth and place it against the inside of the cheek.

Now you can slowly squirt Hemangiol® from the syringe directly into your baby's mouth.

Do not lie the child down immediately after the administration.

10



10 - CLEAN THE SYRINGE

Do not dismantle the syringe. Rinse the empty syringe after each use into a glass of clean water:

1. Take a glass of clean water
2. Pull the plunger in
3. Discard the water into your sink
4. Repeat this cleaning process 3 times.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
<https://sideeffects.health.gov.il>.

In addition, you can report side effects to Perrigo via the following address:
www.perrigo-pharma.co.il

This guide, format and content, was updated and approved by the Ministry of Health in August 2020



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Perrigo

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DERMATOLOGIE