

HEMANGIOL® 3.75 mg/mL Oral Solution

Propranolol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hemangiol®.

It does not contain all the information that is known about Hemangiol®.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of giving your child Hemangiol® against the benefits this medicine is expected to have.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Hemangiol® is used for

Hemangiol® is used to treat a condition in infants called hemangioma.

A hemangioma is a collection of extra blood vessels that have formed a lump in or under the skin. A hemangioma can be superficial or deep.

It is sometimes called a 'strawberry mark' because the surface of a hemangioma looks a bit like a strawberry.

Hemangiol® contains the medicine, propranolol which belongs to a group of medicines known as beta-blockers. Beta-blockers are used to treat a

variety of heart and blood vessel conditions.

Your doctor may have prescribed Hemangiol® for another reason.

Ask your doctor if you have any questions about why Hemangiol® has been prescribed for your child.

This medicine is only available with a doctor's prescription.

Before Hemangiol® is given to your child

When it must not be given to your child

Do not give Hemangiol® if your child:

- is born prematurely and has not reached the corrected age of 5 weeks. (The corrected age is worked out by subtracting the number of weeks your child was premature from your child's actual age, i.e. the age of your child minus the number of weeks premature);
- has an allergy to propranolol or any of the ingredients listed at the end of this leaflet. An allergic reaction can include a rash, itching, hives, shortness of breath, wheezing, or difficulty breathing;
- asthma or a history of breathing difficulties;
- has a slow heart beat for their age. Check with your doctor if you are not sure;

- has a heart problem (such as disorders of the heart rhythm and heart failure);
- has very low blood pressure.
- has circulation problems which make the toes and fingers numb and pale;
- is prone to low blood sugar levels;
- has high blood pressure caused by a tumour on the adrenal gland. This is called, 'phaeochromocytoma'.

If you are breastfeeding your child and you are taking medicines that must not be used with Hemangiol® (see "Taking other medicines"), do not give Hemangiol® to your child.

Hemangiol® must not be used after the expiry date printed on the pack. The expiry date refers to the last day of that month.

If this medicine is taken after the expiry date has passed, it may not work as well.

Do not use Hemangiol® if the packaging is torn or shows signs of tampering.

If your medicine has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether Hemangiol® should be given to your child, talk to your doctor.

Before Hemangirol® is given to your child

Tell your doctor if your child has any medical conditions or a family history of any medical conditions, especially the following:

- if your child has liver or kidney problems. Hemangirol® is not recommended in children with liver or kidney impairment.
- if your child has allergies to any other medicines, foods, preservatives or dyes;
- if your child has psoriasis (a skin condition that produces red, dry plaques of thickened skin). Hemangirol® may make the psoriasis worse.
- If your child has diabetes or low blood sugar; in which case, your child's blood sugar level should be measured more frequently;
- if your child has PHACE syndrome (a condition involving haemangioma and blood vessel abnormalities including blood vessels of the brain), as Hemangirol® may increase the risk of stroke;
- if your child has asthma or serious breathing problems;
- heart problems or heart defects;
- low blood pressure;
- circulation problems.

It may not be safe for your child to have Hemangirol® if they have any of these conditions.

Tell your doctor if your child has not been feeding well or has been vomiting.

Taking other medicines

Tell your doctor or pharmacist about any other medicines that your child is being given, has recently been given or might be given, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Hemangirol® may interfere with each other. They may affect how well Hemangirol®

works or Hemangirol® may affect how well they work.

Your child may need to take different amounts of other medicines, or may need to take different medicines. Your doctor or pharmacist will advise you.

Know the medicines that your child takes. Keep a list of these medicines with you to show the doctor and pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid giving your child while your child is taking Hemangirol®.

Do not give your child any new medicine while your child is taking Hemangirol®. Talk to your doctor first.

If you are breastfeeding your child, it is important to tell your doctor, pharmacist or nurse which medicines you yourself are taking.

These medicines can pass into your breast milk and interfere with the treatment of your child.

In particular, tell your doctor or pharmacist if you (if you are breastfeeding) or your child are taking:

- medicines for diabetes;
- medicines for heart problems such as an irregular heart beat, chest pain, high blood pressure or heart failure;
- medicines used to treat anxiety and depression as well as more serious health problems, and epilepsy;
- medicines used to treat pain and inflammation;
- medicines to treat tuberculosis;
- medicines to treat pain and inflammation;
- medicines used to lower lipids in the blood;
- medicines used for anaesthesia.

If you have not told your doctor or pharmacist about any of the above, tell them before you start giving your child Hemangirol®.

How to give Hemangirol®

Give Hemangirol® to your child exactly as your doctor has prescribed.

How much to give

Your doctor will decide what dose to give, how often and when to give Hemangirol® to your child.

The recommended dose of Hemangirol® will be reached gradually with weekly increases under medical supervision. Dosing is based on your baby's weight. Your doctor will readjust the dose as your child's weight changes.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or bottle, ask your doctor or pharmacist for help.

How to give it

Give Hemangirol® twice a day, one dose in the morning and one late afternoon with at least 9 hours between each dose, during or immediately after feeding your child.

Give Hemangirol® directly into your child's mouth using the oral syringe supplied with the bottle.

If necessary, you may mix the dose of Hemangirol® with a small amount of your child's milk or apple or orange juice suitable for your child's age and give it to your child in a baby's bottle. Do not mix the dose of Hemangirol® with a full bottle of milk or juice.

For children weighing up to 5 kg you may mix the Hemangirol® dose with one teaspoonful of milk (approximately 5 mL).

For children weighing more than 5 kg, the dose may be mixed with a tablespoonful of milk or juice (approximately 15 mL).

Use the mixture within 2 hours of preparation.

Feed your child regularly while your child is taking Hemangiol®.

If your child is not feeding or is vomiting, then do not give Hemangiol® to your child until their feeding is back to normal and tell your doctor.

If your child spits up a dose or if you are uncertain whether he/she got all of the medicine, do not give another dose. Just wait until the next scheduled dose.

The dose of Hemangiol® and the child's food must be given by the same person to avoid the risk of hypoglycaemia (low sugar levels in the blood). If different people are involved, good communication is essential in order to ensure the safety of your child.

How long to give it

Continue giving Hemangiol® to your child for as long as your doctor tells you. Treatment will usually last for a six month period.

If you forget to give it

Do not give a double dose to make up for the dose you missed. Give the next dose of Hemangiol® when you are meant to then continue giving it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have given too much (overdose)

Contact your doctor immediately or the Poisons Information Centre (in Australia telephone 131 126; in New Zealand telephone 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital immediately, if you think that too much Hemangiol® has been given to your child.

Your child may need urgent medical attention.

While your child is taking Hemangiol®

Things you must do

Call your doctor immediately or seek emergency medical assistance if your child shows any signs such as fatigue, coldness, pallor, bluish-coloured skin or fainting while taking Hemangiol®.

Hemangiol® can lower blood pressure (hypotension) and slow heart rate (bradycardia). That is why your child will be kept under close medical supervision with clinical and heart monitoring for 2 hours after the first dose or after a dose increase. Then, your doctor will regularly examine your child during treatment.

To avoid the risk of hypoglycaemia, your child must be fed regularly during treatment. If your child is not feeding or is vomiting, treatment with Hemangiol® should be stopped temporarily. DO NOT RESUME TREATMENT WITH HEMANGIOL® UNTIL YOUR CHILD HAS STOPPED VOMITING AND IS FEEDING NORMALLY AGAIN.

Hemangiol® may cause low blood sugar (hypoglycaemia) or mask the warning signs of low blood sugar, especially if the baby is not feeding, vomiting or in the case of overdose.

These signs may be minor: pallor, drowsiness, sweating, shaking, palpitations, anxiety, hunger, difficulty waking up; or major: excessive sleeping, difficulty getting a response, poor feeding, drop in body temperature, convulsions (fits), brief pauses in breathing, loss of consciousness.

If your child shows any signs of hypoglycaemia while taking Hemangiol®, make your child drink a liquid containing sugar and stop the treatment with Hemangiol® until you have informed your doctor. If symptoms persist, call your doctor immediately or seek emergency medical assistance.

If your child is coughing, breathing quickly or having difficulty breathing, wheezing or has bluish-coloured skin, stop treatment and contact your doctor immediately or seek emergency medical assistance.

These are symptoms of bronchospasm (narrowing of the airways).

If your child is going to have surgery, tell the surgeon or anaesthetist that your child is taking Hemangiol®. Hemangiol® may need to be discontinued at least 48 hours before the anaesthesia.

If your child is about to be started on any new medicine, remind your doctor and pharmacist that your child is taking Hemangiol®.

Tell any other doctors, dentists and pharmacists who are treating your child that your child is taking Hemangiol®.

Things you must not do

Do not give Hemangiol® to any other child, even if they seem to have the same condition.

Do not give Hemangiol® to treat any other complaints unless your doctor tells you to.

Side effects

Tell your doctor as soon as possible if your child becomes unwell while taking Hemangiol®.

Like other medicines, Hemangiol® can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by the following list of possible side effects. Your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Very common side effects (may affect more than 1 in 10 people):

- bronchitis (inflammation of the bronchial tubes)
- sleep disorders (insomnia, poor quality of sleep, difficulties waking up)
- vomiting
- diarrhoea

Common side effects (may affect up to 1 in 10 people):

- bronchospasm (difficulty breathing)
- bronchiolitis (inflammation of the small bronchi with breathing difficulties and wheeze in the chest)
- decreased blood pressure
- reduced appetite
- agitation, nightmares, irritability
- somnolence (drowsiness)
- cold extremities (hands and/or feet)
- constipation
- stomach pain
- erythema (skin redness or flushing)

Uncommon side effects (may affect up to 1 in 100 people):

- heart conduction or rhythm disorders (slow or uneven heart beats)
- urticaria (rash, itching or hives on the skin)
- alopecia (hair loss)
- decreased blood sugar levels
- reduction of the number of white blood cells

The frequency of the following side effects is not known:

- convulsions (fits) linked to abnormally low blood sugar levels (hypoglycaemia),
- abnormally slow heart rate (bradycardia)
- low blood pressure
- very low levels of white blood cells that fight infection
- circulation problems which make the toes and fingers numb and pale

- Elevated levels of potassium in the blood

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else which may be causing your child to be unwell.

After using Hemangiol®

Storage

The bottle of Hemangiol® solution should be stored in a dry place where the temperature stays below 30°C. Do not freeze it.

Use within 2 months of opening.

Always keep the bottle of Hemangiol® solution in its outer carton to protect it from light.

Store the oral syringe with the bottle in the outer carton between each use.

Do not store Hemangiol® or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop the treatment with Hemangiol®, or it has passed its expiry date, ask your pharmacist what to do with any of the medicine left over. Do not dispose of this medicine via wastewater or household waste. This will help to protect the environment.

Product description

What it looks like

Hemangiol® is a clear, colourless to pale yellow solution with a fruity odour. It comes in an amber glass

bottle with a child-resistant screw cap and is supplied with a 5 mL dispensing oral syringe.

Ingredients

Active ingredient:

- propranolol hydrochloride

Other ingredients:

- hydroxyethylcellulose
- saccharin sodium
- citric acid monohydrate
- purified water
- strawberry (proprietary ingredient number: 109091) and vanilla (proprietary ingredient number: 109044) flavours

Distributor

Hemangiol® is supplied in Australia by:

Pierre Fabre Australia Pty Limited
Suite 601, 504 Pacific Highway, St Leonards,
NSW 2065

Australian Registration Number:
212274

This leaflet was prepared in June 2015.