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To report any suspected adverse reactions to, kindly contact:
National Pharmacovigilance Centre at Saudi Food and Drug Authority (SFDA):

SFDA call centre: 19999

E-mail: npc.drug@sfd.gov.sa

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SCAN ME



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Marketing Authorization Holder Contact Information: Saudi AmaroX Industrial Company

Ms. Shahad Alshalan

Pharmacovigilance Specialist

Al Jamiyah Street – Al Malaz – Riyadh Code 12629, Saudi Arabia.

Phone: +966 11 226 8850

Mobile: +966 559687331

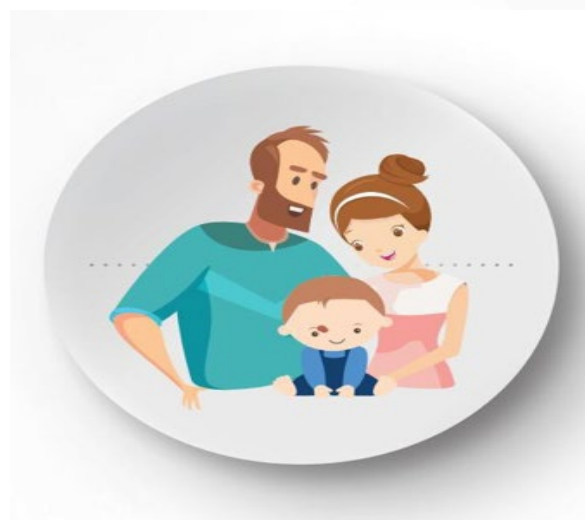
Email: PVsaudi@amaroxpharma.com

202409

Properal (Propranolol Hydrochloride)

4.28mg/ml, oral solution

Propranolol oral solution for Treatment of
infantile hemangiomas



Guide for caregiver

This guide is a mandatory part of the marketing authorization for Propranolol Hydrochloride and was commissioned as an additional risk-minimizing measure to reduce the risk of serious adverse events and increase the benefit-risk ratio of Propranolol Hydrochloride. This guide to the use of Propranolol Hydrochloride is intended to ensure that patients are aware of and consider the special safety requirements when using propranolol in the treatment of infantile hemangiomas.



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Your child's doctor has prescribed Propranolol Hydrochloride an oral solution specifically designed to treat infantile hemangiomas in infants that require oral treatment.

Please read the package leaflet included in the carton of Propranolol Hydrochloride carefully before you start treatment with Propranolol Hydrochloride. It is important that everyone involved in your child's care receives this information.

Like many other medicines, Propranolol Hydrochloride can cause unwanted side effects.

This guide brochure contains important information on how to identify and address the following risks associated with treatment with Propranolol Hydrochloride .

- Low blood sugar/hypoglycemia
- Difficulty breathing/bronchospasm
- Potential risk of administration error

These risks exist throughout the entire duration of treatment with propranolol , regardless of the child's age, and even when treatment is resumed after a possible interruption.

Administer this medication exactly as directed; do not change the dose of Propranolol Hydrochloride on your own. Never try to make up for a missed dose later.

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Low blood sugar or hypoglycemia

Infants are susceptible to hypoglycemia, also known as low blood sugar or hypoglycemia, especially:

- when the need for glucose is increased (cold, stress, infections/labored breathing).
- during periods of restricted food intake (poor oral feeding, concurrent infection, teething).

At normal doses, **Propranolol Hydrochloride** may **potentiate hypoglycemia and/or mask some warning signs of hypoglycemia**, particularly if the infant is fasting, underfeeding, or vomiting. The same applies to an overdose of **Propranolol Hydrochloride**.

HOW DO I RECOGNIZE THE SIGNS OF HYPOGLYCAEMIA?

The warning signs of hypoglycemia are paleness, sweating, fatigue, tremors, rapid heartbeat, anxiety, hunger, difficulty waking up.

If hypoglycemia is not treated appropriately, it can worsen. Possible signs include:

- more sleep than usual,
- difficulty in responding,
- poor food intake (reduced appetite),
- reduced body temperature,
- Convulsions (seizures),
- short breathing breaks,
- Unconsciousness.

These signs can be masked by Propranolol Hydrochloride and treated with some known Side effects of propranolol can be confused:

- Difficulty sleeping and waking up due to effects on the central nervous system,
- Paleness, tiredness and weakness due to low blood pressure (hypotension).

If you notice any changes in your child's behavior, contact your doctor.

WHAT SHOULD I DO IF I SUSPECT HYPOGLYCAEMIA?



If your child shows signs of a Hypoglycemia indicates:



- **Stop treatment.**



- If your child is conscious and able to swallow, give him a sugary solution to drink.



- If your child is unconscious or unable to swallow, go straight to the hospital.



- If symptoms persist, call a doctor immediately or go directly to the hospital.

HOW CAN THE RISKS OF HYPOGLYCAEMIA BE AVOIDED?

The risk of hypoglycemia remains the same throughout the entire treatment period, regardless of your child's age. Furthermore, this risk may recur when treatment is resumed. **It is important to follow the dosage recommendations, administering Propranolol Hydrochloride during or shortly after meals. To avoid the risk of hypoglycemia, it is also important not to administer the dose before bedtime.**

(See full instructions for use on page 14).



Low blood sugar or hypoglycemia

How should your child be fed during treatment?



- Give Propranolol Hydrochloride **during or immediately after a meal** (breast milk, infant formula or solid food) to avoid long periods without food intake and do not administer the last dose before bedtime.



- Your child's meal and Propranolol Hydrochloride should be administered by the same person. If you can't prevent multiple people from being involved, it's important that everyone involved communicates well.



- Skip the dose if your child is not eating properly, is vomiting, or develops another illness (e.g., diarrhea or infections such as a gastrointestinal infection). Do not give your child Propranolol Hydrochloride again until they have eaten enough food without vomiting.



- Stop treatment immediately and consult a doctor if your child shows cold-like symptoms associated with difficulty breathing and/ or shortness of breath (see difficulty breathing or bronchospasm).

You must give your child exactly the dose of Propranolol Hydrochloride that was prescribed:

- Never change the dose on your own.
- If you forget to give your child a dose of propranolol , do not give it, but simply wait until the next scheduled dose.
- If you have given your child too much Propranolol Hydrochloride , please contact a doctor immediately.

How can hypoglycemia during sleep be avoided?

- Give the first dose in the morning and the last dose no later than late afternoon, always with a meal. Administer Propranolol Hydrochloride not directly before going to bed.

If you have any questions about Propranolol Hydrochloride or any other medications you or your child are taking, please consult your doctor.





Difficulty breathing or bronchospasms

Propranolol Hydrochloride may cause constriction of the airways and thus lead to difficulty breathing (similar to asthma), especially in connection with bronchial infections in winter.

HOW DO I KNOW THAT MY CHILD IS HAVING DIFFICULTIES WHEN BREATHING?

Signs of difficulty breathing include:
Cough, rapid or labored breathing or wheezing with or without
bluish Discoloration of the skin.

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



If your child has difficulty breathing or wheezes, **stop treatment and contact a doctor immediately.**

Treatment with Propranolol Hydrochloride can be resumed on the recommendation of the doctor once your child has fully recovered.

Summary



LOW BLOOD SUGAR LEVEL/HYPOGLYCAEMIA

- Give Propranolol Hydrochloride during or immediately after a meal and administer the Do not take the last dose immediately before going to bed.
- Your child's meal and Propranolol Hydrochloride should be administered by the same person to avoid administration errors. If other people are involved, at least good communication must be ensured.
- Skip the dose if your child isn't eating properly, is vomiting, or develops another illness (e.g., diarrhea or infections such as a gastrointestinal infection). Only give your child Propranolol Hydrochloride again after they have eaten enough food without vomiting.
- Stop treatment immediately and consult a doctor if your child shows cold-like symptoms associated with difficulty breathing and/or shortness of breath.

SIGNS	MEASURE
Early signs (may be hidden)	
pallor	
Sweat	
fatigue	
Tremble	
Palpitations (perceptible heartbeat, usually fast or irregular)	1. Stop treatment
Angst	2. Give sugar solution to drink, if your child is conscious and can swallow
Hunger	
Waking problems	
Signs of worsening	
More sleep than usual	3. If symptoms persist, contact a doctor immediately or go directly to the hospital
Difficulty in responsiveness (apathy)	
Poor food intake (reduced appetite)	
Reduced body temperature	
Emergency	
Convulsions (seizures)	
Short breathing breaks	
unconsciousness	



DIFFICULTY BREATHING/BRONCHOSPASMS

SIGNS	MEASURE
Cough	1. Stop treatment
Rapid or labored breathing	2. Consult a doctor immediately
Wheezing	3. Treatment with Propranolol Hydrochloride can be resumed on the doctor's recommendation once your child has fully recovered.
With or without bluish skin	

Use of Propranolol Hydrochloride

HOW DID THE DOCTOR DECIDE WHICH DOSE OF PROPRANOLOL HYDROCHLORIDE MY CHILD SHOULD RECEIVE?

The amount of Propranolol Hydrochloride you give your child depends on their body weight and is therefore specifically tailored to your child. Propranolol Hydrochloride should be administered to your child twice daily, once in the morning and once in the late afternoon . A specific amount of Propranolol Hydrochloride solution is measured in milligrams (mg) of the active ingredient using the enclosed oral syringe. There should be at least 9 hours **between the two daily doses**.

Your child will initially receive a low dose, which will be slowly increased each week over a period of 3 weeks until the final effective dose is reached.

Any dose increase may only be ordered by the doctor during the scheduled weekly appointments. At these appointments, you will be informed of the new dose of Propranolol Hydrochloride you will administer to your child.

Because your child grows and gains weight rapidly, the amount of Propranolol Hydrochloride your child receives must be adjusted according to their body weight. Your child will need to receive a larger amount of Propranolol Hydrochloride regularly to achieve the same effect. **This adjustment will be made by the doctor at least once a month.**

PRESCRIBED EFFECTIVE DOSE IN MG

You must give your child exactly the amount of Propranolol Hydrochloride prescribed . Never change the dose you give your child on your own.

WHAT SHOULD I DO IF I FORGET TO GIVE MY CHILD PROPRANOLOL??

If you forget to give your child a dose of Propranolol Hydrochloride, **do not give another dose**, but simply wait until the next scheduled dose.

WHAT SHOULD I DO IF I GIVE MY CHILD TOO MUCH PROPRANOLOL HYDROCHLORIDE?

If you have given your child too much Propranolol Hydrochloride , **please contact your doctor immediately.**

NEVER ATTEMPT TO MAKE UP A MISSED DOSE LATER.

WHAT SHOULD I DO IF MY CHILD STOPS TAKING PROPRANOLOL ?

If your child refuses to take Propranolol Hydrochloride , you can mix the medicine **with a small amount of infant milk** (breast milk or infant formula) or age-appropriate apple/orange juice, as described below, and administer it in a baby bottle:

For children up to 5 kg, mix Propranolol Hydrochloride with 1 teaspoon (about 5 ml) of infant milk.

For children over 5 kg, mix Propranolol Hydrochloride with 1 tablespoon (approximately 15 ml) of infant formula or age-appropriate apple/orange juice. The mixture should be administered within 2 hours. Do not mix Propranolol Hydrochloride with an entire bottle of milk or fruit juice.

MIX THE MEDICINE WITH A SMALL AMOUNT OF INFANT MILK OR FRUIT JUICE.



Instructions for use

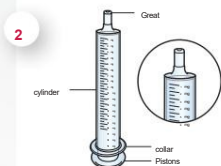


1 - REMOVE THE ITEMS FROM THE OUTER CARTON

The outer carton contains the following parts that you need to administer the medicine:

- The glass bottle containing 120 ml of Propranolol, oral solution
- The oral syringe with graduation in milligrams, which is enclosed with the medicine

Remove the bottle and oral syringe from the outer carton and remove the syringe from the plastic bag.



2 - DOSE CHECK

Check the Propranolol Hydrochloride dose in milligrams (mg) as prescribed by your doctor. Look for this number on the Oral syringe.



3 - OPENING THE BOTTLE

The bottle comes with a child-resistant cap. To open, press down on the plastic cap while turning the cap counterclockwise (to the left). Do not shake the bottle before use.



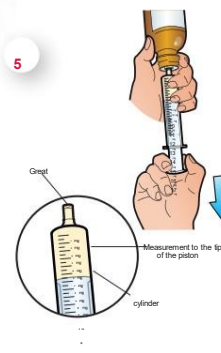
4 - INSERTING THE SYRINGE INTO THE BOTTLE

Insert the tip of the oral syringe into the bottle, holding it upright, and push the syringe plunger down completely.

Do not remove the syringe adapter from the bottle neck.

Use only the oral syringe provided with the medicine to measure and administer the dose.

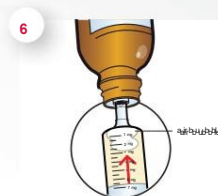
Do not use a spoon or any other dispensing device.



5 - DOSE COLLECTION

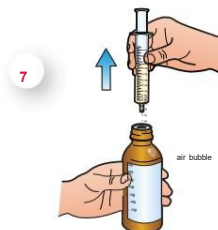
Turn the bottle, along with the oral syringe inside, upside down.

Use the syringe plunger to draw up the required milligrams.



6 - CHECK FOR AIR BUBBLES

If you see air bubbles in the syringe, hold the syringe upright, push the plunger up far enough to completely expel any large air bubbles, and readjust the dose as prescribed by your doctor.



7 - REMOVAL OF THE SYRINGE

Place the bottle upright again and remove the syringe from the bottle. Be careful, push the

Do not put the plunger into the syringe.



8 - CLOSING THE BOTTLE

Replace the plastic cap on the bottle by turning it clockwise (to the right).

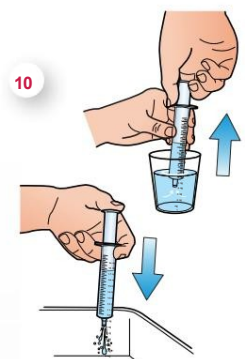


9 - GIVE Propranolol Hydrochloride TO YOUR CHILD

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

Now you can slowly inject the Propranolol Hydrochloride from the syringe directly into your baby's mouth.

Do not lay your child down immediately after administration



10 - CLEANING THE SYRINGE

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

1. Take a glass of clean water
2. Push the plunger in, then pull the syringe with water
3. Dispose of the water in your sink
4. Repeat this cleaning process three times.