

Patient Information Leaflet

Panadol Baby 120mg/5mL Oral Suspension PARACETAMOL

Package Leaflet: Information for the user.

Please read right through this leaflet before you start using this medicine. This medicine is available without prescription, but you still need to use Panadol Baby suspension carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- If you have any further questions, ask your pharmacist.
- You must contact a doctor if symptoms worsen or do not improve after 1 day.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Panadol Baby is and what it is used for
2. Before you give Panadol Baby to the child
3. How should you give Panadol Baby to the child
4. Possible side effects
5. How to store Panadol Baby
6. Further information

1. What Panadol Baby is and what it is used for

Panadol Baby suspension contains **paracetamol** which is an analgesic (a painkiller that reduces aches and shivers) and antipyretic (it reduces temperature when a child has a fever).

Panadol Baby suspension relieves the pain of teething, toothache and sore throats and reduces the fever often associated with colds and 'flu and childhood infections such as chickenpox, whooping cough, measles and mumps.

2. Before you give Panadol Baby to the child

<Cross symbol> Do not give Panadol Baby to the child:

- If the child is allergic to **paracetamol** or any of the ingredients listed in Section 6.
- If the child is taking any **other medicines containing paracetamol**.
- If the child has a known intolerance to the sugar called fructose.

<Exclamation point symbol> Take special care. Please speak to your doctor before you give Panadol Baby to the child if:

- The child suffers from liver or kidney problems.
- The child is underweight or malnourished.
- The baby was born prematurely and is under 3 months.

During treatment with Panadol Baby, tell your doctor straight away if:

- The child has severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or suffers from malnutrition or is also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular

doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea), and being sick (vomiting).

Contact a doctor immediately if the child gets a combination of these symptoms.

Other medicines and paracetamol

<Exclamation point symbol> Please speak to your doctor before you give Panadol Baby to the child if:

- The child is taking metoclopramide or domperidone (used to treat nausea and vomiting) or cholestyramine (used to treat high cholesterol).
- The child is taking warfarin or other drugs used to prevent blood clotting.
- The child is taking any prescribed drugs or is under the care of a doctor.
- Please tell your doctor or pharmacist if your baby is taking or has recently taken any other medicines, including medicines obtained without a prescription
- The child is taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

<Exclamation point symbol> Pregnancy and breastfeeding

If necessary, Panadol Baby can be used during **pregnancy**. You should use the lowest possible dose for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced. You can take this product whilst **breastfeeding**.

<Exclamation point symbol> Important information about some of the ingredients in Panadol Baby:

- This medicine contains 750 mg sorbitol in each 5 ml, which is equivalent to 150 mg/ml. Sorbitol (E420) is a source of fructose. If the child has a known intolerance to some sugars, contact your doctor before using this medicinal product. Sorbitol may cause gastrointestinal discomfort and have a mild laxative effect.
- This medicinal product contains maltitol syrup (E965). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. Maltitol may cause a mild laxative effect.
- Methyl parahydroxybenzoate (E218) and Propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed).

3. How should you give Panadol Baby to the child

How to use the measuring device:

1. Push the plunger in to fully close the dosing device.
2. Turn the bottle upside down and gently pull the correct dose for your child.
- 3 Turn the bottle upright and remove from the bottle by gently twisting it.

After use you should clean the syringe with warm water and dry it. Sterilisation is not needed.

Check the tables below to see how much of the medicine to use.

- For oral use only.
- It is important to **shake the bottle** for at least 10 seconds before use.
- Never give more medicine than shown in the table.
- Always use the measuring device supplied with the pack, and do not overfill.
- Do not give with any other paracetamol-containing products.
- Always use the lowest effective dose to relieve symptoms.

Age: 2-3 months	Dose
1. Post-vaccination fever	2.5 mL If necessary, after 4-6 hours, give a second 2.5 mL dose
2. Other causes of Pain and fever <u>only</u> if - Weighs over 4 kg - Born after 37 weeks	

- Do not give to babies less than 2 months of age.
- Do not give more than 2 doses.
- Leave at least 4 hours between doses.
- If further doses are needed, talk to your doctor or pharmacist.

Child's Age	How Much	How Often (in 24 hours)
3-6 months	2.5 mL	4 times
6 - 24 months	5 mL	4 times
2 - 4 years	7.5 mL	4 times
4 - 8 years	10 mL	4 times
8 - 10 years	15 mL (10 mL + 5 mL)	4 times
10 - 12 years	20 mL (10 mL + 10 mL)	4 times

- Do not give more than 4 doses in any 24 hour period.
- Leave at least 4 hours between doses.
- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

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Not recommended for babies under 2 months except under medical advice. Do not exceed stated dose.

If symptoms do not improve within 24 hours consult your doctor.

Prolonged use except under medical supervision may be harmful. This product should only be used when clearly necessary.

If you give too much to the child

Immediate medical advice should be sought in the event of overdose because of the risk of irreversible liver damage.

4. Possible side effects

Like all medicines, Panadol Baby can cause side effects, although not everybody gets them. Very rare cases of serious skin reactions have been reported.

Stop using this medicine and tell your doctor immediately if:

Very rare (may affect up to 1 in 10,000 people)

- the child experiences allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- the child experiences a skin rash or peeling, or mouth ulcers.
- the child has previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experiences a similar reaction with this product.
- the child experiences unexpected bruising or bleeding.
- the child experiences changes in blood tests that measure the function of their liver.

Other side effects may include a severe reduction in white blood cells which makes infections more likely.

Not known frequency (frequency cannot be estimated from the available data):

- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Panadol Baby

Do not store above 30°C.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date (EXP) shown on the carton and bottle label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

Active Ingredients: Each 5mL contains **Paracetamol** 120mg.

Other Ingredients: Sorbitol ((70% liquid) non crystallising), Xanthan gum, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), citric acid anhydrous, tri-sodium citrate dihydrate, glycerine, strawberry flavour, disodium EDTA, sucralose, Maltitol syrup, Purified Water.

Panadol Baby is an opaque to translucent, white to slightly brownish suspension.

Panadol Baby suspension is contained in a 60mL or 100mL amber glass bottle, which is packed into a carton with a 10 mL measuring device (syringe) in plastic (polyethylene and polypropylene), consisting of a barrel (body) & plunger (slider). Not all pack sizes may be marketed.

Product Authorisation Holder is:

Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland and all enquiries should be sent to this address.

Manufactured by:

Haleon Germany GmbH, Barthstrasse 4, D-80339 Munich, Germany.

Product Authorisation number is: PA 678/39/3.

Leaflet revised in August 2025.