



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

Panadol Baby suspension contains **paracetamol** which is an analgesic (a pain killer 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 chicken pox, whooping cough, measles and mumps.

2. Before you give Panadol Baby to the child



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.

Take special care with Panadol Baby



Please see 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.
- The child has a **severe infection** as this may increase the risk of **metabolic acidosis**. Signs of metabolic acidosis include:
 - deep, rapid, difficult breathing
 - feeling sick (nausea), being sick (vomiting)
 - loss of appetite

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

Taking other medicines



Please see 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.



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**.



Important information about some of the ingredients in Panadol Baby:

- If the child has a known intolerance to some sugars, contact your doctor before use as this product contains maltitol syrup and sorbitol.
- The preservatives Sodium methylparaben (E219), Sodium ethylparaben (E215) and Sodium propylparaben (E217) may cause allergic reactions (possibly delayed).
- The colouring agent Hexacol Carmoisine Supra (E122) may cause allergic reactions.

3. How should you give Panadol Baby to the child

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 spoon supplied with the pack.
- Do not overfill the spoon.
- Do not give with any other paracetamol-containing products.
- Always use the lowest effective dose to relieve the child's symptoms.

Age: 2 – 3 months	Dose
1. Post-vaccination fever	One 2.5 mL measure
2. Other causes of Pain and Fever only if <ul style="list-style-type: none">• Weighs over 4 kg• Born after 37 weeks	If necessary, after 4-6 hours, give a second 2.5 mL dose

- 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	One 2.5 mL measure	4 times
6 – 24 months	One 5 mL spoonful	4 times
2 – 4 years	One 5 mL spoonful and one 2.5 mL measure	4 times
4 – 8 years	Two 5 mL spoonfuls	4 times
8 – 10 years	Three 5 mL spoonfuls	4 times
10 – 12 years	Four 5 mL spoonfuls	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.



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 overdosage 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 (affects less than 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.

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 25°C. Do not freeze.

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 spoonful contains **Paracetamol** 120mg.

Other Ingredients: Hexacol Carmoisine Supra (E122), Malic Acid, Keltrol F (Xanthan Gum), Maltitol Syrup, Strawberry Flavour L10055, Sorbitol Liquid (Crystallising), Sodium methylparaben (E219), Sodium ethylparaben (E215), Sodium propylparaben (E217), Sorbitol Powder, Citric Acid, Purified Water.

Panadol Baby is an opaque, pink liquid with an odour of strawberry.

Panadol Baby suspension is contained in a 60mL or 100mL amber glass bottle.

Product Authorisation Holder is:

GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, CityWest Business Campus, Dublin 24, Ireland and all enquiries should be sent to this address.

Manufactured by:

Farmaclair, 440 Avenue du General de Gaulle, 14200 Herouville Saint Clair, France.

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