

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### PANADOL BABY

120 mg / 5 ml syrup

PARACETAMOL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What PANADOL BABY is and what it is used for
2. Before you take PANADOL BABY
3. How to take PANADOL BABY
4. Possible side effects
5. How to store PANADOL BABY
6. Further information

#### 1. WHAT PANADOL BABY IS AND WHAT IS IT USED FOR

PANADOL BABY syrup 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 syrup 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 TAKE PANADOL BABY

##### **Do not give PANADOL BABY to a child**

- If the child is allergic (hypersensitive) to Paracetamol or to any of the other ingredients in this medicine (see section 6).
- If the child has a known intolerance to the sugar (fructose)
- With other products containing paracetamol
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##### **Take special care with PANADOL BABY**

Tell your doctor if:

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

### **Taking other medicines**

Please tell your doctor or pharmacist if your baby is taking or has recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor before you give PANADOL BABY to a child if the child is taking:

- 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.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant see your doctor before you take **PANADOL BABY**.

You can take this product whilst breastfeeding.

### **Important information about some of the ingredients of 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 TO TAKE PANADOL BABY**

Always take PANADOL BABY exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

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.

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"><li>• Weighs over 4 kg</li><li>• Born after 37 weeks</li></ul>	<b>One 2.5 mL measure</b> <b>If necessary, after 4-6 hours, give a second 2.5 mL dose</b>	
<ul style="list-style-type: none"><li>- Do not give to babies less than 2 months of age.</li><li>- Do not give more than 2 doses.</li><li>- Leave at least 4 hours between doses.</li><li>- If further doses are needed, talk to your doctor or pharmacist.</li></ul>		
Childs age	How much	How often

3-6 months	<b>One 2.5 mL measure</b>	4 times
6-24 months	<b>One 5 mL spoonful</b>	4 times
2-4 years	<b>One 5 mL spoonful and one 2.5 mL measure</b>	4 times
4-8 years	<b>Two 5 mL spoonfuls</b>	4 times
8-10 years	<b>Three 5 mL spoonfuls</b>	4 times
10-12 years	<b>Four 5 mL spoonfuls</b>	4 times
<ul style="list-style-type: none"> <li>• Do not give more than 4 doses in any 24 hour period.</li> <li>• Leave at least 4 hours between doses.</li> <li>• Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.</li> </ul>		

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 more PANADOL BABY than you should***

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

Talk to your doctor or pharmacist if you have any additional questions.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

***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 or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE PANADOL BABY**

Keep out of the reach and sight of children.

Do not store above 25 °C. Do not freeze.

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**

### ***What PANADOL BABY contains***

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.

### ***What PANADOL BABY looks like and contents of the pack***

**PANADOL BABY** 120 mg / 5 ml syrup

PANADOL BABY is an opaque, pink liquid with an odour of strawberry. PANADOL BABY suspension is contained in 100mL amber glass bottle.

### ***Regime of dispensing***

The medicine is issued without doctor's prescription.

### ***Manufacturer***

Wellcome Limited, Great West Road 980, Brentford, Middlesex TW8 9GS, England