

**PATIENT INFORMATION LEAFLET**  
**PAEDIATRIC PARACETAMOL ELIXIR BP**  
**Paracetamol 120 mg/5 ml**

**Read all of this leaflet carefully because it contains important information for you and your child.**

This medicine is available without prescription; however, you still need to give Paediatric Paracetamol Elixir carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your child's symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Paracetamol Elixir is and what it is used for
2. Before you give Paracetamol Elixir to your child
3. How to give Paracetamol Elixir to your child
4. Possible side effects
5. How to store Paracetamol Elixir
6. Further information

**1. WHAT PARACETAMOL ELIXIR IS AND WHAT IT IS USED FOR**

Paediatric Paracetamol Elixir ("Paracetamol Elixir") contains paracetamol to relieve pain and reduce high temperatures. Paracetamol Elixir can be used in babies and children for the treatment of mild or moderate pain and feverishness, and also in babies who develop fever after vaccination.

**2. BEFORE YOU GIVE PARACETAMOL ELIXIR TO YOUR CHILD**

**DO NOT give Paracetamol Elixir if your child is taking any other paracetamol containing products, other flu, cold, cough or decongestant products, or alcohol.**

**DO NOT give Paracetamol Elixir to your child if he/she:**

- is allergic (hypersensitive) to paracetamol, or any of the other ingredients of Paracetamol Elixir (see Section 6 and end of Section 2).
- has kidney or liver problems

If you are not sure about any of the above, please consult your doctor.

**Take special care with Paracetamol Elixir**

Seek advice from your doctor or pharmacist:

- if your child is under 2 months of age
- if the symptoms persist.

**Taking other medicines**

Tell your doctor or pharmacist if your child is taking, or has recently taken, any other medicine, even those obtained without a prescription, but especially medicines which:

- are to treat 'flu' or a cold, containing paracetamol and/or a decongestant
- thin the blood (e.g. warfarin)
- control nausea and vomiting (e.g. domperidone or metoclopramide)
- reduce levels of cholesterol and other fats in the blood (e.g. colestyramine).
- treat epilepsy (e.g. anti-convulsants)
- have been prescribed by your doctor to improve sleep (e.g. barbiturates), or for anxiety or depression (e.g. tricyclic antidepressants)

**The effects of alcohol may be increased whilst taking Paracetamol Elixir.**

Avoid alcohol when taking this medicine.

**Pregnancy and breast-feeding**

This medicine is intended for use in children.

Ask your doctor or pharmacist for advice before taking any medicines during pregnancy or breastfeeding.

**Driving and using machines**

This medicine is intended for use in children. However, it should be noted that Paracetamol Elixir is not expected to affect ability to drive or operate machinery.

**Important information about some of the ingredients of Paracetamol Elixir**

Paracetamol Elixir contains:

- **Ethanol:** This medicinal product contains 0.5 g of ethanol (alcohol) per 5 ml dose, equivalent to 12 ml beer or 5 ml wine per 5 ml dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.
- **Sorbitol:** if your child has an intolerance to some sugars, contact your doctor before giving this medicine.
- **Propylene glycol:** may cause alcohol-like symptoms, so you should supervise your child after giving this medicine.

### 3. HOW TO GIVE PARACETAMOL ELIXIR TO YOUR 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
- Do not overfill the spoon
- Always use the spoon supplied with the pack
- Do not give this medicine with any other paracetamol-containing product

Age	Dose
For post-vaccination fever for babies aged between 2 - 3 months	One 2.5 ml spoonful (small end) If necessary, after 4-6 hours, give a second 2.5 ml dose
<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>	

Child's Age	How Much	How often (in 24 hours)
3 - 6 months	One 2.5 ml spoonful (small end)	4 times
6 - 24 months	One 5 ml spoonful (large end)	4 times
2 - 4 years	One 5.0 ml spoonful (large end) and one 2.5 ml spoonful (small end)	4 times
4 - 8 years	Two 5 ml spoonfuls (large end)	4 times
8 - 10 years	Three 5 ml spoonfuls (large end)	4 times
10 - 12 years	Four 5 ml spoonfuls (large end)	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><li>• If symptoms persist, please consult your doctor</li></ul>		

#### If your child takes more of this medicine than they should:

Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage.

#### If you forget to give this medicine:

If you miss a dose give it as soon as you remember and take any remaining doses for that day at evenly spaced times. Do not take a double dose to make up for the missed dose.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol Elixir can cause side effects although not everybody gets them.

You or your child may notice the following:

- **rash, itchy skin, swelling of the lips, eyes, tongue, or difficulty in breathing, which may be signs of an allergic reaction. STOP giving Paracetamol Elixir to your child immediately.**
- blood disorders

**If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.**

### 5. HOW TO STORE PARACETAMOL ELIXIR

**Keep all medicines out of reach and sight of children.**

Do not store above 25°C. Store in the original container. Keep the container in the outer carton.

Do not use this medicine after the expiry date which is stated on the label and/or carton. 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 Paracetamol Elixir contains

Each 5ml of Paracetamol Elixir contains:

- The **active ingredient:** paracetamol 120 mg.
- The **other ingredients** are: ethanol, propylene glycol, glycerol (E422), sorbitol solution, acesulfame K, saccharin sodium (E954), xanthan gum, quinoline yellow (E104), banana liquid flavour, sodium citrate, citric acid and purified water (see end of Section 2 for further information).

#### What Paracetamol Elixir looks like and contents of the pack:

Paracetamol Elixir is a pale clear to slightly opalescent yellow viscous liquid with an odour and taste of banana presented in 70 ml, 100 ml, 150 ml and 200 ml amber glass bottles with pilfer-proof screw caps. A 2.5 ml/5 ml measuring spoon is provided.

#### Marketing Authorisation Holder and Manufacturer:

Pinewood Laboratories Limited, Ballymacarby, Clonmel, Co. Tipperary, Ireland.

Product Licence Number: PL 04917/0008

Date of revision:

August 2011

23LF

**PATIENT INFORMATION LEAFLET**  
**PAEDIATRIC PARACETAMOL ELIXIR BP**  
**Paracetamol 120 mg/5 ml**

**Read all of this leaflet carefully because it contains important information for you and your child.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours or your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Paracetamol Elixir is and what it is used for
2. Before you give Paracetamol Elixir to your child
3. How to give Paracetamol Elixir to your child
4. Possible side effects
5. How to store Paracetamol Elixir
6. Further information

**1. WHAT PARACETAMOL ELIXIR IS AND WHAT IT IS USED FOR**

Paediatric Paracetamol Elixir ("Paracetamol Elixir") contains paracetamol to relieve pain and reduce high temperatures. Paracetamol Elixir can be used in babies and children for the treatment of mild or moderate pain and feverishness, and also in babies who develop fever after vaccination.

**2. BEFORE YOU GIVE PARACETAMOL ELIXIR TO YOUR CHILD**

**DO NOT give Paracetamol Elixir if your child is taking any other paracetamol containing products, other flu, cold, cough or decongestant products, or alcohol.**

**DO NOT give Paracetamol Elixir to your child if he/she:**

- is allergic (hypersensitive) to paracetamol, or any of the other ingredients of Paracetamol Elixir (see Section 6 and end of Section 2).
- has kidney or liver problems

If you are not sure about any of the above, please consult your doctor.

**Take special care with Paracetamol Elixir**

Seek advice from your doctor or pharmacist:

- if the symptoms persist.

**Taking other medicines**

Tell your doctor or pharmacist if your child is taking, or has recently taken, any other medicine, even those obtained without a prescription, but especially medicines which:

- are to treat 'flu' or a cold, containing paracetamol and/or a decongestant
- thin the blood (e.g. warfarin)
- control nausea and vomiting (e.g. domperidone or metoclopramide)
- reduce levels of cholesterol and other fats in the blood (e.g. colestyramine).
- treat epilepsy (e.g. anti-convulsants)
- have been prescribed by your doctor to improve sleep (e.g. barbiturates), or for anxiety or depression (e.g. tricyclic antidepressants)

**The effects of alcohol may be increased whilst taking Paracetamol Elixir.**

Avoid alcohol when taking this medicine.

**Pregnancy and breast-feeding**

This medicine is intended for use in children.

Ask your doctor or pharmacist for advice before taking any medicines during pregnancy or breastfeeding.

**Driving and using machines**

This medicine is intended for use in children. However, it should be noted that Paracetamol Elixir is not expected to affect ability to drive or operate machinery.

**Important information about some of the ingredients of Paracetamol Elixir**

Paracetamol Elixir contains:

- **Ethanol:** This medicinal product contains 0.5 g of ethanol (alcohol) per 5 ml dose, equivalent to 12 ml beer or 5 ml wine per 5 ml dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.
- **Sorbitol:** if your child has an intolerance to some sugars, contact your doctor before giving this medicine.
- **Propylene glycol:** may cause alcohol-like symptoms, so you should supervise your child after giving this medicine.

### 3. HOW TO GIVE PARACETAMOL ELIXIR TO YOUR 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
- Do not overfill the spoon
- Always use the spoon supplied with the pack
- Do not give this medicine with any other paracetamol-containing product

Age	Dose
For post-vaccination fever for babies aged between 2 - 3 months	One 2.5 ml spoonful (small end) If necessary, after 4-6 hours, give a second 2.5 ml dose
<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>	

Child's Age	How Much	How often (in 24 hours)
3 - 6 months	One 2.5 ml spoonful (small end)	4 times
6 - 24 months	One 5 ml spoonful (large end)	4 times
2 - 4 years	One 5.0 ml spoonful (large end) and one 2.5 ml spoonful (small end)	4 times
4 - 8 years	Two 5 ml spoonfuls (large end)	4 times
8 - 10 years	Three 5 ml spoonfuls (large end)	4 times
10 - 12 years	Four 5 ml spoonfuls (large end)	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><li>• If symptoms persist, please consult your doctor</li></ul>		

#### If your child takes more of this medicine than they should:

Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage.

#### If you forget to give this medicine:

If you miss a dose give it as soon as you remember and take any remaining doses for that day at evenly spaced times. Do not take a double dose to make up for the missed dose.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol Elixir can cause side effects although not everybody gets them.

You or your child may notice the following:

- **rash, itchy skin, swelling of the lips, eyes, tongue, or difficulty in breathing, which may be signs of an allergic reaction. STOP giving Paracetamol Elixir to your child immediately.**
- blood disorders

**If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.**

### 5. HOW TO STORE PARACETAMOL ELIXIR

**Keep all medicines out of reach and sight of children.**

Do not store above 25°C. Store in the original container. Keep the container in the outer carton.

Do not use this medicine after the expiry date which is stated on the label and/or carton. 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 Paracetamol Elixir contains

Each 5ml of Paracetamol Elixir contains:

- The **active ingredient:** paracetamol 120 mg.
- The **other ingredients** are: ethanol, propylene glycol, glycerol (E422), sorbitol solution, acesulfame K, saccharin sodium (E954), xanthan gum, quinoline yellow (E104), banana liquid flavour, sodium citrate, citric acid and purified water (see end of Section 2 for further information).

#### What Paracetamol Elixir looks like and contents of the pack:

Paracetamol Elixir is a pale clear to slightly opalescent yellow viscous liquid with an odour and taste of banana presented in 500 ml, 1 litre or 2 litre amber glass bottles with pilfer-proof screw caps, or in 500 ml, 1 litre or 2 litre HDPE bottles with tamper evident caps.

#### Marketing Authorisation Holder and Manufacturer:

Pinewood Laboratories Limited, Ballymacarby, Clonmel, Co. Tipperary, Ireland.

Product Licence Number: PL 04917/0008

Date of revision: August 2011

23LF