

GALPAMOL FOR CHILDREN PARACETAMOL 120MG/5ML ORAL SUSPENSION

PATIENT INFORMATION LEAFLET

Read this leaflet carefully because it contains important information.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your child's symptoms worsen or do not improve after 3 days.

IN THIS LEAFLET:

1. What this medicine is for
2. Before you give this medicine
3. How to give this medicine
4. Possible side effects
5. Storing the medicine
6. Further information

1 WHAT THIS MEDICINE IS FOR

Paracetamol relieves pain and brings down high temperatures (reduces fever).

Galpamol for Children Paracetamol 120mg/5ml Oral Suspension is used for the relief of:

- mild to moderate pain in young children, including teething pain and fever.

2 BEFORE YOU GIVE THIS MEDICINE

Do not give Galpamol for Children Paracetamol 120mg/5ml Oral Suspension:

- if your child is allergic to paracetamol, or any of the other ingredients listed in section 6.

Do not give anything else containing paracetamol while giving this medicine.

Talk to your pharmacist or doctor before giving if:

- your child suffers from severe liver or kidney disease.

If your child is taking other medicines:

Talk to your pharmacist or doctor before giving this medicine if your child is taking any of the following:

- medicines for nausea or sickness, such as metoclopramide or domperidone.
- colestyramine for high cholesterol or high blood fats.
- warfarin (or other medicines used to thin the blood and reduce the risk of clotting). The risk of bleeding may be increased if your child takes paracetamol daily over a long period of time. However your child can take occasional doses of paracetamol.

Important information about some of the ingredients of this medicine:

Galpamol for Children Paracetamol 120mg/5ml Oral Suspension contains hydrogenated glucose syrup (which contains maltitol and sorbitol). If you have been told by your doctor that your child has an intolerance to some sugars, consult your doctor before giving this medicine. Each 5ml spoonful contains 3.25g of hydrogenated glucose syrup. This provides 7.48 kcal per 5ml spoonful. Hydrogenated glucose syrup may have a mild laxative effect.

Galpamol for Children Paracetamol 120mg/5ml Oral Suspension also contains sodium methylparaben (E219) and sodium propylparaben (E217), which may cause allergic reactions, possibly delayed.

Adults taking this medicine should be aware of these factors and additionally:

Talk to your pharmacist or doctor before taking if:

- you suffer from alcoholic liver disease.

Pregnancy and breast feeding:

Talk to your doctor before taking paracetamol if you are pregnant. You can take paracetamol while breast feeding.

3 HOW TO GIVE THIS MEDICINE

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

- For oral use only
- It is important to **shake the bottle** or massage the sachet for at least 10 seconds before use in order to mix the contents
- Never give more medicine than shown in the table
- Do not overfill the spoon
- Always use the spoon supplied with the pack

CHILD'S AGE	HOW MUCH	HOW OFTEN
3 – 6 months	One 2.5 mL spoonful (small end)	4 times (in 24 hours)
6 – 24 months	One 5 mL spoonful (large end)	4 times (in 24 hours)
2 – 4 years	One 5 mL spoonful (large end) and one 2.5 mL spoonful (small end)	4 times (in 24 hours)
4 – 8 years	Two 5 mL spoonfuls (large end)	4 times (in 24 hours)
8 – 10 years	Three 5 mL spoonfuls (large end)	4 times (in 24 hours)
10 - 12 years	Four 5 mL spoonfuls (large end)	4 times (in 24 hours)
<ul style="list-style-type: none">• 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.		

Further information overleaf.

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"> • 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. 	

Do not give more medicine than the label tells you to.
If your child does not get better, talk to your doctor.

Talk to a doctor at once if your child takes too much of this medicine even if they seem well.
This is because too much paracetamol can cause delayed, serious liver damage.

4 POSSIBLE SIDE EFFECTS

Like all medicines, paracetamol can cause side effects, although not everybody gets them. Side effects are rare with paracetamol.

Stop giving the medicine and contact your doctor immediately if you notice:

- skin rashes or other signs of allergic reaction such as itching, swelling of the lips, tongue or throat, or difficulty in breathing.
- unexpected bruising or bleeding, persistent tiredness or an increase in the number of infections (e.g. sore throats) which your child gets. These are possible signs of changes in the blood.

Reporting of side effects

If you or your child 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5 STORING THE MEDICINE

Store below 25°C. Do not refrigerate. Protect from light.

Do not use after the expiry date shown on the carton.

Keep out of the sight and reach of children.

6 FURTHER INFORMATION

What is in this medicine:

The active ingredient is: Paracetamol 120mg per 5ml.

Other ingredients are: glycerol (E422), microcrystalline cellulose, carboxymethylcellulose sodium, sodium methylparaben (E219), sodium propylparaben (E217), citric acid anhydrous, saccharin sodium, strawberry flavour containing propylene glycol, acesulphame K, carmine (E120), glycerine, potassium hydroxide, hydrogenated glucose syrup (which contains sorbitol and maltitol (E965)), xanthan gum, purified water.

What this medicine looks like and contents of the pack:

Galpamol for Children Paracetamol 120mg/5ml Oral Suspension is a pink suspension with a strawberry taste and odour.

Galpamol for Children Paracetamol 120mg/5ml Oral Suspension is available in bottles containing 70, 100, 150 or 200ml of suspension, or in sachets containing a single 5ml dose which are packed into cartons containing 4, 5, 8, 10, 12, 15, 16, 20, 24, 25, 48, 50, 96 or 100 sachets (not all packs may be marketed, bottles of 200ml and pack sizes of 20, 24, 25, 48, 50, 96 or 100 sachets are only available from your pharmacist).

Marketing Authorisation Holder:

Galpharm Healthcare Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Manufacturer:

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