JUNIOR PARACETAMOL 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

teething pain and fever.

- 5. Storing the medicine
- 6. Further information

1 WHAT THIS MEDICINE IS FOR

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

Junior Paracetamol Suspension is used for the relief of:

• mild to moderate pain in young children, including

2 BEFORE YOU GIVE THIS MEDICINE

Do not give Junior Paracetamol 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:

Junior Paracetamol 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.

Junior Paracetamol 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 breastfeeding:

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

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

Children aged 3 months - 12 years:

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 (5 ml + 2.5 ml)	4 times
4 – 8 years	10 ml (5 ml + 5 ml)	4 times
8 – 10 years	15 ml (5 ml + 5 ml + 5 ml)	4 times
10 - 12 years	20 ml (5 ml + 5 ml + 5 ml + 5 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.

Further information overleaf

For the relief of fever after vaccination at 2, 3 and 4 months

2.5ml. This dose may be given up to 4 times a day at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine 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.

Very rare cases of serious skin reactions have been reported.

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:

purified water.

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,

What this medicine looks like and contents of the pack:

Junior Paracetamol Suspension is a pink suspension with a strawberry taste and odour.

Junior Paracetamol 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 Limited, Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Manufacturer:

Galpharm International Limited, Elmhirst Park, Middle Field Road, Barnsley, South Yorkshire, S75 4LS, United Kingdom.

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