



Australian Government
Department of Health
Therapeutic Goods Administration

Children's Panadol 1-5 years suspension

Retail level recall - paracetamol does not match specification

4 December 2013

GlaxoSmithKline (GSK), in consultation with the TGA, is recalling two batches of Children's Panadol 1-5 years suspension as a small proportion of bottles contain higher levels of paracetamol than specified.

The active ingredient in Children's Panadol 1-5 years suspension is paracetamol. Paracetamol has been used to treat fever since the 1950s and is available in many different forms for adults and children.

Paracetamol is safe and effective when taken as directed on the label. However, if taken either in excess of the recommended dose for more than a few days, the unwanted effects can be severe.

The two affected batches were dispatched from GSK between September and November 2013 as a precautionary measure.

The identified batches are:

- Children's Panadol 1-5 years suspension (strawberry / 200mL) - (identified by JR13086)
- Children's Panadol 1-5 years suspension (orange / 100mL) - (identified by JR130697)

While a small proportion of each batch may contain paracetamol levels that are higher than specified, this does not pose a risk to children when the product is used according to the directions on the label.

No other Children's Panadol products are affected by this issue.

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Information for consumers

The higher levels of paracetamol in the two affected batches may result in doses that are over the recommended extent that they pose risks to children when the product is used according to the directions on the label.

Parents and carers should ensure that they follow the dosing instructions on the label.

As with all medicines, consumers should always read the label and use only as directed.

For Children's Panadol 1-5 years suspension the label instructs users to:

- shake bottle, use the measuring device provided to accurately measure the correct dose.
- this dose may be repeated if necessary, every 4 hours.
- do not give more than four doses in one day or within any 24-hour period.
- do not use for more than 48 hours at a time except on medical advice.

If you have given more paracetamol than recommended above, contact the Poisons Information the nearest hospital emergency department. Do this even if your child does not seem sick.

If you have a bottle from one of the two affected batches and still have concerns, you can contact GSK (1800 022 373 or 1300 732 873). GSK will either organise for a replacement product to be sent to you or, if urgent, GSK can provide a replacement from your local pharmacy. Alternatively a refund can be provided.

Information for hospitals and pharmacies

If you possess or supply Children's Panadol 1-5 years suspension check for the batch number list.

If you have any stock from the affected lots, quarantine it or remove it from shelves and then contact your local health authority. A recall process to be followed.

Information for all other health professionals

If you are recommending the use of paracetamol, advise parents and carers to always follow the label instructions. Be alert to the possibility that accidental overdose may exist when the product has not been used as directed.

Reporting problems

Consumers and health professionals are encouraged to report problems with medicines or vaccines. Your feedback will contribute to the TGA's monitoring of these products.

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to report any concerns about a possible adverse event associated with a medicine or vaccine.

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URL: <http://www.tga.gov.au/safety/alerts-medicines-childrens-panadol-suspension-131204.htm>