PANADOL Children Suppositories 6 Months - 5 Years & 5 - 12 Years

Active ingredient(s): Paracetamol 125 mg & Paracetamol 250 mg

Consumer Medicine Information (CMI)

This leaflet provides important information about using Panadol Children Suppositories. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Panadol Children Suppositories.

Where to find information in this leaflet:

- 1. Why am I using Panadol Children Suppositories?
- 2. What should I know before I use Panadol Children Suppositories?
- 3. What if my child is taking other medicines?
- 4. How do I use Panadol Children Suppositories?
- 5. What should I know while using Panadol Children Suppositories?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Panadol Children Suppositories?

Panadol Children Suppositories contains the active ingredient paracetamol. Paracetamol is an analgesic that works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Panadol Children Suppositories are used for the fast effective temporary relief of pain and discomfort associated with: immunsiation, earache, cold & flu symptoms, teething, headache. Paracetamol also reduces fever.

2. What should I know before I use Panadol Children Suppositories?

Warnings

Do not use Panadol Children Suppositories if:

 you are allergic paracetamol, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Do not use this medicine if your child is taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Always read and follow the label.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether your child should start using this medicine, talk to your pharmacist or doctor.

Check with your doctor or pharmacist if your child:

- Liver or kidney disease
- Are underweight or malnourished
- A severe infection, as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- · deep, rapid, difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite

Contact a doctor immediately if your child gets a combination of these symptoms.

Please see your doctor if your child's symptoms do not improve.

Keep out of sight and reach of children.

During treatment, your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Consider taking the lowest effective dose for the shortest period of time.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Panadol Children Suppositories and affect how it works.

- Warfarin, a medicine used to prevent blood clots
- Metoclopramide, a medicine used to control nausea and vomiting
- Medicines used to treat epilepsy or fits
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Alcohol
- Probenecid, a medicine used to treat gout or sometimes given with an antibiotic
- Cholestyramine, a medicine used to treat high cholesterol levels in the blood

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect Panadol Children Suppositories.

4. How do I use Panadol Children Suppositories?

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your pharmacist or doctor for help.

Do not exceed the stated dose.

Use the smallest dose that you need to treat your child's symptoms and use the medicine for the shortest period of time necessary.

How much to take

PANADOL CHILDREN 6 MONTHS – 5 YEARS SUPPOSITORIES

Children 6 months to 4 years with an average weight of 8 to 16 kg: Use 1 suppository every 4 to 6 hours as needed. Do not use more than 4 suppositories in 24 hours.

Children 4 to 5 years with an average weight of 16 to 18 kg: Use 2 suppositories every 4 to 6 hours as needed. Do not use more than 8 suppositories in 24 hours.

Do not use in children below the age of 2 except on medical advice.

PANADOL CHILDREN 5 - 12 YEARS SUPPOSITORIES

Children 5 to 9 years with an average weight of 18 to 28 kg: Use 1 suppository every 4 to 6 hours as needed. Do not use more than 4 suppositories in 24 hours.

Children 9 to 12 years with an average weight of 28 to 41 kg: Use 2 suppositories every 4 to 6 hours as needed. Do not use more than 8 suppositories in 24 hours.

Do not use in children below the age of 5 except on medical advice.

How long to use Panadol Children Suppositories

 Panadol Children Suppositories should be used in children for up to 48 hours unless a doctor has told you to give it for longer.

How to use Panadol Children Suppositories

For ease of insertion, the suppository can be inserted just before insertion.

If possible, ask your children to go to the toilet and empty their bowels before using the suppository.

Suppositories work best if the bowels are emptied.

Tear the blister along the perforated line between each suppository. You can then remove the suppository by pulling each side of the blister apart from the top.

Follow these steps to use a suppository:

- 1. Wash your hands thoroughly with soap and water.
- 2. Put on a disposable glove, if desired. They are available from pharmacies.
- 3. Moisten the suppository by dipping it briefly in cool water.
- Lie your child on their side and raise their knee to their chest.
- 5. Push the suppository gently, blunt end first, into their rectum, or back passage.

- 6. Keep your child lying down for a few minutes so that the suppository dissolves.
- 7. Throw away used materials and wash your hands thoroughly.

If you use too much Panadol Children Suppositories

If you think that you have used too much Panadol Children Suppositories, your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Panadol Children Suppositories?

Things you should do

Talk to your pharmacist or doctor if your child's symptoms do not improve.

Remind any doctor, dentist or pharmacist you visit that you are using Panadol Children Suppositories.

Things you should not do

Do not give Panadol Children Suppositories for more than 48 hours unless a doctor has told you to.

Do not take more than the recommended dose unless your doctor tells you to.

Do not use Panadol Children Suppositories to treat any other complaints unless your pharmacist or doctor tells you to.

Looking after your medicine

Keep your medicine in the original pack until it is time to take it

Keep your medicine in a cool dry place where the temperature stays below 25C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If your child does experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

[Serious/rare] side effects

Serious side effects	What to do
Shortness of breath Wheezing or difficulty breathing Swelling of the face, lips, tongue, throat or other parts of the body Rash, peeling, itching or hives on the skin or mouth ulcers Unexplained bruising or bleeding	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

The above list includes very serious side effects. Your child may need urgent medical attention or hospitalisation. These side effects are very rare for low doses of this medicine and when used for a short period of time.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects your child experiences, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Panadol Children Suppositories contains

Active ingredient (main ingredient)	Paracetamol 125 mg
Other ingredients (inactive ingredients)	Hard fat
Potential allergens	NIL

Active ingredient (main ingredient)	Paracetamol 250 mg
Other ingredients	Hard fat
(inactive ingredients)	

Potential allergens NIL

Do not take this medicine if you are allergic to any of these ingredients.

What Panadol Children Suppositories looks like

Panadol Children Suppositories 125 mg (AUST R 332713) are white or almost white cylindrical shape with a rounded top. They come in strip packs of 10 suppositories.

Panadol Children Suppositories 250 mg (AUST R 332714) are white or almost white cylindrical shape with a rounded top. They come in strip packs of 10 suppositories.

Who distributes Panadol Children Suppositories

GlaxoSmithKline Consumer Healthcare 82 Hughes Avenue, Ermington NSW

This leaflet was prepared in January 2020.