Panadol Children 5-12 Years Elixir

Paracetamol 48 mg/mL

INFORMATION LEAFLET

Please read this information before you start using this medicine.

What is in this leaflet

This leaflet answers some common questions about PANADOL CHILDREN 5-12 YEARS ELIXIR. It does not contain all the available information.

It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits.

If you have any concerns about your child using this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine. You may need to read it again.

What PANADOL CHILDREN 5-12 YEARS ELIXIR is used for

The active ingredient in this medicine is paracetamol.

Paracetamol is used for the effective temporary relief of pain, fever and discomfort associated with

- Immunisation
- Earache
- Cold & flu symptoms
- Teething
- Headache

Paracetamol also reduces fever.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given it to your child for another reason.

Before you use PANADOL CHILDREN 5-12 YEARS ELIXIR

When you must not use it

Do not give more than the recommended dose as it may cause serious harm to the liver.

Do not use PANADOL CHILDREN 5-12 YEARS ELIXIR if you have an allergy to:

• Any of the ingredients listed at the end of this leaflet

Do not give 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.

This medicine contains sorbitol. People with rare hereditary problems of fructose intolerance should not take this medicine.

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.

Before you start to use it

Tell your pharmacist or doctor if your child has or has had any of the following medical conditions:

- Liver or kidney problems
- Underweight or malnourished You may need to avoid using this product altogether or limit the amount of paracetamol that you give to your child.
- Has a severe illness, severe infection including blood infection or is severely malnourished as this may increase the risk of metabolic acidosis (a blood and fluid abnormality).

 Signs of metabolic acidosis include:
 - deep, rapid, difficult breathing
 - feeling sick (nausea), being sick (vomiting)
 - loss of appetite
 - drowsiness

Contact a doctor immediately if you think your child may be affected.

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

Keep out of sight and reach of children.

Ask your pharmacist or doctor about using paracetamol if you are pregnant or plan to become pregnant, or breastfeeding.

Paracetamol may be used during pregnancy and if you are breastfeeding but you should always consult your doctor first.

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

If you have not told your pharmacist or doctor about any of the above, tell them before you use PANADOL CHILDREN 5-12 YEARS ELIXIR.

Using other medicines

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

Some medicines and paracetamol may interfere with each other. These include:

- Warfarin or similar medicines used to thin the blood
- 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
- Flucloxacillin (an antibiotic) due to a serious risk of blood and fluid abnormality (metabolic acidosis)

Your pharmacist and doctor will have more information on these and other medicines to be careful with or avoid while using this medicine.

How to use PANADOL CHILDREN 5-12 YEARS ELIXIR

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/bottle, ask your pharmacist or doctor for help.

Do not exceed the stated dose and do not take more frequently than every four hours. Use the smallest effective dose that you need to treat your symptoms and use the medicine for the shortest period of time necessary.

How much to use

<u>Children 1 to 2 years with an</u> <u>average weight of 10 to 12 kg:</u> Give 3 to 4 mL every 4 to 6 hours if required. Do not give more than 4 times in 24 hours.

<u>Children 2 to 3 years with an</u> <u>average weight of 12 to 14 kg:</u> Give 4 mL every 4 to 6 hours if required. Do not give more than 4 times in 24 hours.

Children 3 to 4 years with an average weight of 14 to 16 kg: Give 4 to 5 mL every 4 to 6 if required. Do not give more than 4 times in 24 hours.

Children 4 to 5 years with an average weight of 16 to 18 kg:
Give 5 to 6 mL every 4 to 6 hours if required Do not give more than 4 times in 24 hours.

Children 5 to 6 years with an average weight of 18 to 20 kg: Give 6 mL every 4 to 6 hours if required. Do not give more than 4 times in 24 hours.

Children 6 to 7 years with an average weight of 20 to 22 kg:
Give 6 to 7 mL every 4 to 6 hours if required. Do not give more than 4 times in 24 hours.

Children 7 to 8 years with an average weight of 22 to 25 kg:
Give 7 to 8 mL every 4 to 6 hours if required. Do not give more than 4 times in 24 hours.

<u>Children 8 to 9 years with an</u> <u>average weight of 25 to 28 kg:</u> Give 8 to 9 mL every 4 to 6 hours if required. Do not give more than 4 times in 24 hours.

<u>Children 9 to 10 years with an</u> <u>average weight of 28 to 32 kg:</u> Give 9 to 10 mL every 4 to 6 hours if required. Do not give more than 4 times in 24 hours. Children 10 to 11 years with an average weight of 32 to 36 kg:

Give 10 to 11 mL every 4 to 6 hours if required. Do not give more than 4 times in 24 hours.

Children 11 to 12 years with an average weight of 36 to 41 kg:
Give 11 to 13 mL every 4 to 6 hours if required. Do not give more than 4 times in 24 hours.

Ask a doctor before use if your child weighs less than 10 kg or more than 41 kg.

Using the measuring cup provided to accurately measure. Calculate the correct dose based on child's weight. If weight is unknown, use the child's age.

How to use it

Shake the bottle thoroughly before use.

Give the medicine with water or fruit juice.

How long to use it

Only give paracetamol to children for up to 48 hours unless a doctor has told you to give it for longer.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that your child or anyone else may have taken too much PANADOL CHILDREN 5-12 YEARS ELIXIR. Do this even if there are no signs of discomfort or poisoning because of the risk of delayed, serious liver damage/failure if left untreated.

They may need urgent medical attention.

While you are using PANADOL CHILDREN 5-12 YEARS ELIXIR

Things you must do

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

Your pharmacist or doctor will assess your child's condition and decide if you should continue to give the medicine.

Things you must not do

Do not give PANADOL **CHILDREN 5-12 YEARS ELIXIR** for more than 48 hours unless a doctor has told you to.

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

Do not use PANADOL **CHILDREN 5-12 YEARS ELIXIR** to treat any other complaints unless your pharmacist or doctor tells you to.

Side Effects

Tell your pharmacist or doctor as soon as possible if your child does not feel well while they are taking PANADOL CHILDREN 5-12 YEARS ELIXIR. This medicine helps most people with various types of pain but they may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your child may need medical attention if they get some of the side effects.

Do not be alarmed by the following lists of side effects. These side effects are rare and your child may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

If any of the following happens, stop using the product, tell your

pharmacist or doctor immediately or go to Accident and Emergency at your nearest hospital:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue, throat or other parts of the body
- Allergic skin reactions such as rash, peeling, itching or hives
- Mouth ulcers
- Unexplained bruising or bleeding
- Symptoms of metabolic acidosis which may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea), being sick (vomiting) and loss of appetite.

The above list includes very serious side effects. Your child may need urgent medical attention or hospitalisation.

Tell your pharmacist or doctor if you notice anything that is making vour child feel unwell.

Other side effects not listed above may also occur in some people.

After using PANADOL CHILDREN 5-12 YEARS SUSPENSION

Storage

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 30°C.

Do not store PANADOL **CHILDREN 5-12 YEARS ELIXIR** or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in a

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product Description

What it looks like

PANADOL CHILDREN 5 – 12 YEARS ELIXIR is a clear, light, red coloured syrupy liquid. It comes in a bottle of 200 mL

Ingredients

PANADOL CHILDREN 5 – 12 YEARS ELIXIR contains 48 mg/mL paracetamol as the active ingredient.

It also contains:

- Glycerol
- Water purified
- Macrogol 1500
- Sorbitol solution (70%) (crystallising)
- Propylene glycol
- Allura red AC
- Saccharin sodium
- Benzoic acid
- Imitation candied sugar
- Potassium sorbate
- Raspberry flavour

Contains: sulfites, saccharin, benzoates, sorbates and sorbitol (7.28 g/52 mL). Products containing sorbitol may have a laxative effect or cause diarrhoea.

AUST R 15506 (PANADOL CHILDREN 5 – 12 YEARS ELIXIR)

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