

Children's Paedamin® Decongestant and Antihistamine Oral Liquid (Children 2-12 years)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Children's Paedamin Decongestant and Antihistamine.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you/your child taking Children's Paedamin Decongestant and Antihistamine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Children's Paedamin Decongestant and Antihistamine is used for?

Children's Paedamin Decongestant and Antihistamine is used to provide fast relief from the symptoms of colds and allergies including:

- **Runny nose**
- **Sneezing**
- **Itchy, watery eyes**
- **Nasal congestion**

Children's Paedamin Decongestant and Antihistamine contains Diphenhydramine Hydrochloride and Phenylephrine Hydrochloride.

Diphenhydramine Hydrochloride belongs to a group of medicines called 'antihistamines'. Antihistamines help reduce allergic symptoms, such as sneezing, runny nose or itchy, watery eyes, by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances that the body is allergic to.

Phenylephrine Hydrochloride belongs to a group of medicines called decongestants.

It works by reducing congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, and making it easier to breathe.

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

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

Before you give Children's Paedamin Decongestant and Antihistamine

When you must not give it

Do not use Children's Paedamin Decongestant and Antihistamine if you/ your child have an allergy to:

- **any medicine containing Diphenhydramine Hydrochloride or other antihistamines**
- **any medicine containing Phenylephrine Hydrochloride**
- **any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include:

- **shortness of breath**
- **wheezing or difficulty breathing**

- **swelling of the face, lips, tongue or other parts of the body**

- **rash, itching or hives on the skin**

Do not take this medicine if you have or have had any of the following medical conditions:

- **narrow angle glaucoma (high pressure in the eyes)**
- **stomach or duodenal ulcer, or other stomach problems**
- **enlarged prostate**
- **bladder problems**
- **very high blood pressure**
- **severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)**

Do not take Children's Paedamin Decongestant and Antihistamine if you are also taking monoamine oxidase inhibitors (MAOI's) or have taken monoamine oxidase inhibitors in the last 14 days. Monoamine oxidase inhibitors are a type of medicine used to treat depression.

Do not take Children's Paedamin Decongestant and Antihistamine if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

Do not give Children's Paedamin Decongestant and Antihistamine to children under 2 years of age.

Do not take 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 you should start taking this medicine, talk to your pharmacist or doctor.

Before you start to give it

Tell your doctor if you/your child have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you/your child have or have had any of the following medical conditions:

- **kidney or liver disease**
- **epilepsy**
- **high blood pressure**
- **overactive thyroid gland**
- **diabetes**
- **heart disease and poor blood flow in the blood vessels of the heart**
- **glaucoma (high pressure in the eyes)**
- **prostate problems**

Tell your pharmacist or doctor if you take sedatives.

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant.

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking Children's Paedamin Decongestant and Antihistamine.

Taking other medicines

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

Some medicines and Children's Paedamin Decongestant and Antihistamine may interfere with each other.

These include:

- **medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants**
- **medicines used to help you sleep or relax (sedatives and hypnotics)**
- **opioid analgesics, medicines used to treat pain**
- **medicines used to treat heart conditions**
- **medicines used to treat high blood pressure**
- **medicines used to treat urinary tract infections and bladder problems**
- **medicines used to treat behavioural disorders**
- **pseudoephedrine, a medicine used to treat congestion**
- **appetite suppressants**

These medicines may be affected by Children's Paedamin Decongestant and Antihistamine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to give Children's Paedamin Decongestant and Antihistamine

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.

How much to give

RECOMMENDED DOSAGE 6-8 HOURLY AS NECESSARY

Age	Body Wt	Dose
2 - 4 yrs	12 - 16 kg	4.0 - 5.5 mL
4 - 6 yrs	16 - 20 kg	5.5 - 7.0 mL
6 - 8 yrs	20 - 23 kg	7.0 - 8.0 mL
8-10 yrs	23 - 28 kg	8.0 - 10 mL
10-12 yrs	28 - 41 kg	10 - 15 mL

Adults and children over 12 years - 15mL every 6 hours when necessary.

Do not give more than the recommended dose.

Do not administer to children under 2 years of age.

When to give it

Give Children's Paedamin Decongestant and Antihistamine 6-8 hourly as necessary. It does not matter if you give Children's Paedamin Decongestant and Antihistamine before or after food.

How long to give it for

If symptoms persist for more than 48 hours or are accompanied by high fever, consult your doctor.

If you forget to give it

If it is almost time for the next dose, just take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking the medicine as recommended.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your pharmacist or doctor.

If you give too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand, call 0800 764 766) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Children's Paedamin Decongestant and Antihistamine. Do this even if there are no signs of discomfort or poisoning.

While you are giving Children's Paedamin Decongestant and Antihistamine

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 condition and decide if you should continue to take the medicine.

Things you must not do

Do not drink alcohol while taking Children's Paedamin Decongestant and Antihistamine.

The sedating effects of alcohol may be increased.

Do not give Children's Paedamin Decongestant and Antihistamine to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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

Things to be careful of

Be careful driving or operating machinery until you know how Children's Paedamin Decongestant and Antihistamine affects you.

This medicine may cause drowsiness in some people. If this happens, do not drive or operate machinery.

Children's Paedamin Decongestant and Antihistamine contains 10.5g of sorbitol per maximum daily dose in adults. Products containing sorbitol may have a laxative effect or cause diarrhoea.

Side Effects

Tell your pharmacist or doctor as soon as possible if you/your child do not feel well while you are taking Children's Paedamin Decongestant and Antihistamine.

This medicine helps most people with the symptoms of colds and allergies, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- **drowsiness or sleepiness**
- **dry mouth, nose and throat**
- **constipation**
- **nervousness and irritability**
- **hallucinations**
- **twitching or jerking muscles**
- **fast heart beat**
- **difficulty sleeping**
- **excitability**
- **restlessness**
- **dizziness**
- **fear or anxiety**
- **tremor**
- **skin rashes**
- **urinary retention**

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Children and people over 65 years of age may have an increased chance of getting side effects.

Tell your doctor as soon as possible if you notice any of the following:

- **difficult or painful urination**
- **seizures (fits)**

The above list includes serious side effects that may require medical attention. These side effects are rare. Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

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

After using Children's Paedamin Decongestant and Antihistamine

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 25°C.

Do not store Children's Paedamin Decongestant and Antihistamine or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-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

Children's Paedamin Decongestant and Antihistamine is a clear colourless oral liquid available in a 200mL PET bottle.

Ingredients

Each 1mL of Children's Paedamin Decongestant and Antihistamine contains the active ingredients:

- **Diphenhydramine Hydrochloride 2.5mg**
- **Phenylephrine Hydrochloride 500mcg**

Children's Paedamin Decongestant and Antihistamine also contains glycerol, water, sorbitol solution, sodium benzoate, sodium cyclamate, sodium citrate, citric acid monohydrate, saccharin sodium and hydroxybenzoates (methylparaben, ethylparaben, propylparaben).

This medicine does not contain alcohol, sugar, lactose, gluten or colourants.

Supplier

Children's Paedamin Decongestant and Antihistamine Oral Liquid
AUST R 160400 is supplied in Australia by:
Care Pharmaceuticals Pty Ltd,
Suite 302, 75 Grafton Street,
Bondi Junction, NSW 2022

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