

Paedamin® Decongestant and Antihistamine Syrup for Children

Consumer Medicine Information

What is Paedamin?

Paedamin is a decongestant preparation. It contains two active ingredients:

Diphenhydramine hydrochloride (an antihistamine) in a concentration of 12.5mg/5mL and Phenylephrine Hydrochloride (a blood vessel constricting agent) in a concentration of 2.5mg/5mL.

There are non active ingredients present and they are, Ethanol (alcohol) 7.2% v/v, sucrose, glycerol, sorbitol, sodium hydroxide, citric acid, purified water, flavourings Imitation Apricot and Imitation Vanilla Essences and vegetable colouring agents Sunset Yellow dye (Supra Yellow) and Brilliant Blue dye.

What is Paedamin used for and how does it work?

Paedamin is recommended for the temporary relief from symptoms of:

- **Colds**
- **Allergy/Sneezing**
- **Nasal and Sinus congestion**
- **Runny nose**
- **Itchy, watery eyes**

The preparation works by reducing the amount of mucous produced in the upper airways, thereby relieving the symptoms of congestion of the nose and sinuses associated with excessive mucous production. Paedamin also helps to reduce coughing. Whilst the constituents do not include any cough suppressants, the Diphenhydramine Hydrochloride does have cough suppressant activity.

Patients with Hay Fever suffer with excessive sneezing, nasal congestion, itching and watering of the eyes. These symptoms are due to inhaled allergens (foreign particles to which the body is allergic) reacting with the body's defence mechanism to release a substance called Histamine. Diphenhydramine Hydrochloride, being an antihistamine, will block the effect of the body's chemicals (Histamine) associated with the allergic response. The Phenylephrine Hydrochloride decreases the size of the blood vessels and thus reduces nasal swelling, reduces mucous production and dries the excessive tear production.

When must Paedamin NOT be taken?

Although Paedamin is unlikely to be taken by adults, it must not be taken if the patient has to drive or operate any machinery. The product can cause drowsiness which in the above circumstances may prove to be dangerous. If alcohol has been consumed, then the symptoms of drowsiness may be enhanced.

Patients who have Hypertension (high blood pressure) or Coronary Artery Disease (a history of heart attacks) and Diabetes must avoid taking this medication. Similarly, it should not be taken by pregnant woman, or whilst breastfeeding.

Patients with known allergy or adverse reactions to any of the ingredients, or hypersensitivity to antihistamines or phenylephrine must not take the preparation.

Patients taking other prescribed medication should consult their doctor or pharmacist before taking Paedamin.

When should you be especially careful while taking Paedamin?

It is best that if you do suffer from any of the following complaints that you check with your doctor prior to self administering this medication:

1. **Hyperthyroidism (Graves Disease)**

2. Prostatic enlargement
3. Glaucoma (High pressure of the eyeball - for which drops are used on a daily basis)
4. When you are taking any anti-depressant medication

Can Paedamin be taken while pregnant or while breast feeding?

Pregnant women and breast feeding mothers should not take Paedamin because of the possibility of the transfer of the active ingredients through to either the unborn child or to the new-born through breast milk.

What are the possible unwanted effects of Paedamin?

In addition to the beneficial effects of Paedamin, it is possible that some unwanted effects may occur. These symptoms are as follows:

- a) Mild drowsiness
- b) Hyperactivity and hallucinogenic effects - these have been reported in patients susceptible to antihistamines
- c) Nausea
- c) Dizziness
- d) Sorbitol may have a laxative effect or cause diarrhoea

Mild drowsiness is not a problem unless it interferes with normal activities. Should any of the other unwanted effects occur, then this medication should be stopped and parents should consult with a doctor on the most appropriate alternative.

How should Paedamin be taken?

Paedamin should only be used as directed by the dosage instructions on both the label and carton. The dosage range is as follows:

Do not administer to children under 2 years of age.

RECOMMENDED DOSAGE 6-8 HOURLY WHEN 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

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

Do not give more than the recommended dose or duration.

It is recommended that patients rinse their mouth after taking the medication. This will rid the oral cavity of any sucrose remaining and thus decrease the possibility of dental caries.

What happens if an overdose of Paedamin is taken?

Symptoms of overdosage may include drowsiness, excitement, hallucinations, convulsions, increased blood pressure or effects on the heart.

Always retrieve the bottle and try to estimate the amount of medication taken and how long ago it would have been consumed and then contact your nearest Poisons Information centre on telephone 13 11 26.

How should Paedamin be stored?

Always keep this medication closed and out of both sight and reach of children. Do not use this medicine after the expiry date shown on the pack.

Keep in a cool dry place below the temperature of 30 deg C.

What packaging is available?

Paedamin is available in a 200mL pack marked with the AUST R 20862 registration number.

Further Information

This may be obtained from your doctor or pharmacist.

Supplier

Care Pharmaceuticals Pty Ltd,
Suite 302, 75 Grafton Street,
Bondi Junction, NSW 2022

This leaflet was amended in 10/2008.