

Painstop for children

NIGHT-TIME PAIN RELIEVER

Consumer Medicine Information

What is Painstop Night-Time Syrup?

Painstop Night-Time Syrup is a multi-component pain relieving preparation. The constituents work together to relieve pain of moderate severity in children.

The maroon coloured syrup contains:

- Paracetamol - 120mg per 5mL
- Codeine Phosphate- 5mg per 5mL
- Promethazine Hydrochloride - 6.5mg per 5mL
- It also contains Ethanol (Alcohol) - 0.5mL per 5mL

The inactive ingredients are

- sodium metabisulfite,
- sorbitol,
- saccharin sodium,
- disodium edetate,
- imitation toffee flavour,
- imitation strawberry flavour,
- propylene glycol and sucrose.

The colouring agents are brilliant blue standard C142090 and amaranth CI16185.

What are the indications for use of Painstop Night-time Syrup?

Painstop Night-Time Syrup is used for the temporary relief of moderately severe pain in children when Paracetamol alone is proving to be inadequate and when sedation is considered beneficial.

Some of the most commonly encountered conditions which give rise to pain of this severity are as follows: acute earache, dental pain, migraine, post-operative pain, pain associated with minor fractures and burns.

Paracetamol and Codeine Phosphate are both pain relieving agents. When combined, they form a potent analgesic mixture. Painstop Night-Time Syrup also contains Promethazine Hydrochloride, an antihistamine which in this instance is used for its sedative properties.

When Painstop Night-Time Syrup should not be taken.

1. Painstop Night-time Syrup must not be given to children under 2 years of age.
2. It should not be given to children suffering from only minor pain and fever.
3. It should not be given to children who have pain, the exact cause of which is not known.
4. It should not be taken for more than 24 hours without medical supervision.
5. It should not be given to children with only fever.
6. It should not be given to children under 6 years of age after surgery to remove tonsils or adenoids to treat sleep apnoea.
7. If you are operating machinery or driving a motor vehicle you should not take Painstop Night-time Syrup as there may be associated drowsiness. Alcohol must be avoided when taking this medication as it may make the degree of drowsiness experienced much greater.

8. Painstop Night-time Syrup should not be taken by pregnant women or breast-feeding mothers.
9. Patients taking other medications, in particular Antihistamine containing products, must check with their doctor or pharmacist about cross reactions which may occur with Painstop Night-Time Syrup and whatever other medication they happen to be currently taking.
10. This product is unsuitable for diabetic patients - unless otherwise advised by a doctor.

How should Painstop Night-Time Syrup be taken?

Painstop Night-time Syrup should be taken strictly as directed as per the dosage regime, or as directed by your doctor.

Not to be given to children under 2 years of age.

Do not exceed 2 doses at night.

- **2 years:** 4mL -5mL
6 -8 hourly
- **3 -4 years:** 6mL -7mL
6 -8 hourly
- **5 -6 years:** 7mL -8mL
6 -8 hourly
- **7 -8 years:** 9mL -10mL
6 -8 hourly

Use as directed.

Do not take with other products containing Paracetamol unless advised to do so by a doctor or pharmacist. As with all sugar containing medicines, it is advised that the mouth be rinsed after dosing as this minimises the incidence of tooth decay. Do not use for more than 24 hours or change dosages without medical supervision.

What happens if too much Painstop Night-Time Syrup is taken?

All medicines should be kept out of sight and the reach of children. If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26) or go to a hospital straight away even if the patient is well because of the risk of delayed, serious liver damage. Paracetamol and Codeine overdose have very serious side effects. Some of the symptoms you may observe will be vomiting, sweating, drowsiness or hyperexcitability, convulsions and the skin turning a dusky colour due to lack of oxygen. Serious liver damage from Paracetamol may take up to 3 days to develop.

What are the possible unwanted effects of Painstop Night-Time Syrup?

Hyperexcitability may occur in some children and it is due to the effect of the antihistamine - Promethazine Hydrochloride. Once again, adjustment of the dose in consultation with your doctor or pharmacist may help.

Allergic reactions to any of the components may also occur. Should there be such a reaction, then please stop taking this medication and consult your doctor or pharmacist immediately.

Codeine Phosphate may cause constipation. A high fluid intake is desirable when taking this medication. This product contains 0.88g/5mL of sorbitol which may have a laxative effect or cause diarrhoea in some people. This is more likely if several products containing sorbitol or related substances are consumed simultaneously.

How should Painstop Night-Time Syrup be stored?

Always keep medicines out of the sight and the reach of children. Do not use this medicine after the expiry date shown on the packaging. Keep in a cool place below 25°C. Do not store in the refrigerator.

What packs are available?

Painstop Night-Time Syrup - AUST R 20864 is available only from your pharmacy, and only in packs containing 100mL and 200mL of medicine.

Further Information

Further information can be obtained from your pharmacist or doctor.

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