

Calpol Night Discontinued in the UK

2 March 2009

What is it used for?

- Relieving the symptoms of colds and flu, such as aches and pains, fever, and runny, stuffy or tickly nose.
- Relieving mild to moderate pain, such as headache, sore throat or teething pain.
- Reducing high temperature (fever).

How does it work?

Calpol night oral solution contains two active ingredients, paracetamol and diphenhydramine hydrochloride.

Paracetamol is a simple painkilling medicine used to relieve mild to moderate pain and fever. Despite its widespread use for over 100 years, we still don't fully understand how paracetamol works to relieve pain and reduce fever. However, it is now thought that it works by reducing the production of prostaglandins in the brain and spinal cord.

The body produces prostaglandins in response to injury and certain diseases. One of the effects of prostaglandins is to sensitise nerve endings, causing pain (presumably to prevent us from causing further harm to the area). As paracetamol reduces the production of these nerve sensitising prostaglandins it is thought it may increase our pain threshold, so that although the cause of the pain remains, we can feel it less.

It is thought paracetamol reduces fever by affecting an area of the brain that regulates our body temperature (the hypothalamic heat-regulating center).

Diphenhydramine is a type of medicine called a sedating antihistamine. It enters the brain in sufficient quantities to cause drowsiness.

Diphenhydramine dries nasal secretions, by stopping a natural body chemical called histamine from binding to its receptors. Histamine is a chemical produced naturally by the body that has many effects, including the production of allergic symptoms, such as a runny nose. Blocking histamine receptors prevents the actions of histamine, which reduces the production of mucus in the nose.

The combination of active ingredients in this medicine is useful for relieving mild to moderate pain such as teething pain, headaches and sore throat, and for relieving the symptoms of feverish colds and flu in children. The relief from symptoms and the mild sedative effect caused by the medicine can also be helpful for aiding restful sleep.

Warning!

- **March 2009:** Over-the-counter cough and cold medicines for children have recently been under review in the UK. New advice is that several cough and cold medicines, including this one, are no longer recommended for children under six years of age. This is because there is no evidence that they work in this age group, and they can potentially cause side effects such as allergic reactions, effects on sleep or hallucinations. The packaging and leaflets for cough and cold medicines will be updated over the next year to reflect this information. When the newly labelled products become available they will only be sold from pharmacies, where advice on using the medicines safely can be given. Products with old labelling that give doses for children under six won't be immediately withdrawn from sale, because there are no immediate safety issues with them and they have been in wide use for decades. However, you should no longer give these medicines to children under six. The new recommendations are part of a long-term package of measures that are being phased in to improve the safe use of cough and cold medicines in children under 12 years of age. If you have just given this medicine to a child under six there is no need to worry, provided they were given the dose recommended on the bottle, but you shouldn't use this medicine for them in the future. Children aged 6 to 12 years can still be given this medicine, because the risk of side effects is reduced in older children as they weigh more, get fewer colds and can also tell you if the medicine is doing them any good. For more advice talk to your pharmacist.
- The recommended dose of this medicine varies depending on the age of your child. Carefully follow the dosage instructions provided with this medicine. Do not exceed the recommended dose. The medicine should be administered carefully using the spoon or measuring device supplied to ensure the child does not receive more than the maximum dose.
- This medicine must not be given with any other cough and cold remedies or paracetamol containing products. Many over-the-counter painkillers and cold and flu remedies contain paracetamol. It is important to check the ingredients of any medicines you buy without a prescription before giving them in combination with this medicine. Seek further advice from your pharmacist.

- An overdose of paracetamol is dangerous and capable of causing serious damage to the liver and kidneys. You should never exceed the dose stated in the information leaflet supplied with the medicine. Immediate medical advice should be sought in the event of an overdose with this medicine, even if your child seems well, because of the risk of delayed, serious liver damage.
- This medicine may cause drowsiness. If your child is affected they should avoid performing potentially hazardous activities such as riding a bike or climbing trees. Alcohol should be avoided.
- If symptoms persist for more than three days consult your doctor.

Use with caution in

- Decreased kidney function.
- Decreased liver function.
- Epilepsy.
- Difficulty passing urine (urinary retention).
- Obstruction of the gut.

Not to be used in

- Children under six years of age.
- Closed angle glaucoma.
- Rare hereditary problems of fructose intolerance (Calpol night contains maltitol and sorbitol).

This medicine should not be used if your child is allergic to one or any of its ingredients. Please inform your doctor or pharmacist if your child has previously experienced such an allergy.

If you feel your child has experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately.

Side effects

Medicines and their possible side effects can affect individual people in different ways. The following are some of the side effects that are known to be associated with this medicine. Just because a side effect is stated here does not mean that all people using this medicine will experience that or any side effect.

- Drowsiness.
- Blurred vision.
- Disturbances of the gut such as constipation, nausea, vomiting or abdominal pain.
- Dry mouth, nose and throat.
- Skin rash.
- Difficulty in passing urine (urinary retention).

The side effects listed above may not include all of the side effects reported by the medicine's manufacturer.

For more information about any other possible risks associated with this medicine, please read the information provided with the medicine or consult your doctor or pharmacist.

How can this medicine affect other medicines?

You should not give your child other cough and cold medicines in combination with this one. Different products may contain the same active ingredient(s) and using more than one at the same time could lead to you exceeding the recommended dose for your child. For further advice talk to your pharmacist.

If your child is already taking any other medicines, including herbal medicines and those bought without a prescription, you should check with your pharmacist before giving this medicine as well, to make sure that the combination is safe.

You should not give your child other medicines that contain paracetamol in combination with this medicine, as this can easily result in exceeding the maximum recommended daily dose of paracetamol. Many cold and flu remedies and over-the-counter painkillers contain paracetamol, so be sure to check the ingredients of any other medicines before giving them with this one.

There may be an increased risk of drowsiness if this medicine is taken in combination with any of the following, which can also cause drowsiness:

- alcohol
- benzodiazepines, eg temazepam, diazepam

- sedating antihistamines, eg promethazine, hydroxyzine, triprolidine, chlorphenamine (these are often found in other non-prescription cough and cold or hayfever remedies)
- sleeping tablets, eg zopiclone
- strong opioid painkillers, eg codeine, dihydrocodeine, morphine
- tricyclic antidepressants, eg amitriptyline.

This medicine should not be given to children who are taking any of the medicines listed above.

There may be an increased risk of side effects such as dry mouth, blurred vision, constipation or difficulty passing urine if this medicine is taken with any of the following medicines:

- anticholinergic medicines for urinary incontinence, eg oxybutynin, flavoxate, tolterodine, propiverine, trospium
- antipsychotic medicines, eg chlorpromazine, clozapine
- antispasmodics, eg atropine, hyoscine
- certain antisickness medicines, eg promethazine, prochlorperazine, meclozine, cyclizine
- muscle relaxants, eg baclofen
- MAOI antidepressants, eg phenelzine, tranylcypromine
- procyclidine
- tricyclic or related antidepressants, eg amitriptyline, maprotiline.

Cholestyramine reduces the absorption of paracetamol from the gut. It should not be taken within an hour of taking paracetamol or the effect of the paracetamol will be reduced.

Metoclopramide and domperidone may increase the absorption of paracetamol from the gut.

Long-term or regular use of paracetamol may increase the anti-blood-clotting effect of warfarin and other anticoagulant medicines, leading to an increased risk of bleeding. This effect does not occur with occasional pain-killing doses.

Other medicines containing the same active ingredients

Calcold six plus Dozol Medised for children

Panadol night

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