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## Information for the user

## Cough & Decongestant Syrup 6 Years Plus (Guaifenesin, Pseudoephedrine Hydrochloride)

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to give it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- The leaflet is written in terms of giving this medicine to your child, but if you are an adult who is intending to take this medicine yourself the information in this leaflet will apply to you as well

### What this medicine is for

This medicine contains Pseudoephedrine, a decongestant, which acts to relieve a stuffy, blocked nose and sinuses. It also contains Guaifenesin, an expectorant, which acts to loosen and relieve phlegm and mucus on the chest.

It can be used to relieve the symptoms of a chesty cough and a blocked nose and sinuses. Simple treatments should be tried first before you give this medicine. Further information on "Treating coughs and colds in children" is provided at the end of this leaflet.

### Before you give this medicine

This medicine can be given to children from the age of 6 years. However, some children should not be given this medicine or you should seek the advice of their pharmacist or doctor first.

#### Do not give:

- If your child is under 6 years
- If your child is allergic to any of the ingredients in this medicine (see "What is in this medicine")
- If your child is allergic to other decongestants
- If your child has severe kidney problems, severe acute (sudden) or chronic (long-term) kidney disease or kidney failure
- If your child has heart or blood vessel disease, including poor circulation in their hands or feet
- If your child has high blood pressure (including that due to a tumour near their kidney), very high blood pressure (severe hypertension) or hypertension not controlled by medication
- If your child has diabetes
- If your child has an overactive thyroid
- If your child has raised pressure in the eye (glaucoma)
- If your child is taking any of these medicines:
  - Monoamine oxidase inhibitors or moclobemide (for depression), or has taken them in the last 14 days
  - Medicines called beta-blockers (normally for heart problems)
  - Other decongestants or cough and cold medicines
- If your child has an intolerance to some sugars, unless your doctor tells you to (this medicine contains maltitol liquid)

If adults take this medicine: do not take in pregnancy and breastfeeding.

#### Talk to your doctor:

- If your child has a long-term cough or asthma (do not give this medicine to your child if they are wheezing or if they are having an asthma attack)

#### Talk to your pharmacist or doctor:

- If your child has other kidney problems (see "Do not give")
- If your child also has a fever, rash or constant headache
- If your child has liver problems or epilepsy (this medicine contains alcohol, which may be harmful to your child)

### Other important information

If your child develops:

- A feverish generalised erythema associated with pustules, stop giving this medicine and contact your doctor or seek medical attention immediately. See section 'Possible side effects'
- Sudden abdominal pain or rectal bleeding may occur with this medicine, due to inflammation of the colon (ischaemic colitis). If your child develops these gastro-intestinal symptoms, stop giving this medicine and contact your doctor or seek medical attention immediately. See 'Possible side effects' section.

- Reduction of blood flow to the optic nerve may occur with pseudoephedrine-containing products. If your child develops sudden loss of vision, stop giving Boots Cough & Decongestant Syrup 6 Years Plus and contact your doctor or seek medical attention immediately. See possible side effects section.

- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Boots Cough & Decongestant Syrup 6 Years Plus immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see "Possible side effects" for symptoms)

The decongestant effect of this medicine may be reduced if you give it for a long time.

This medicine may interfere with the results of some urine tests. If your child has any urine tests, tell the doctor or hospital staff that they are taking this medicine.

If your child goes into hospital for an operation tell the doctor that they are taking this medicine.

**Information about some of the ingredients in this medicine:** This medicine contains maltitol liquid, which may have a mild laxative effect.

**Information for people with diabetes:** This medicine contains 2.7 g of maltitol per 5 ml spoonful. This provides 6 kcal per 5 ml spoonful.

### Information for adults intending to take this medicine

All of the information in this leaflet will apply to you as well.

This medicine may be harmful if you are dependent on alcohol. Each 5 ml spoonful contains 0.2 g alcohol equivalent to 4 ml of beer or 1.7 ml of wine.

**Pregnancy and breastfeeding:** Do not take this medicine.

### If your child takes other medicines

Before you give this medicine, make sure that you tell your pharmacist about ANY other medicines you might be giving to your child at the same time, particularly the following:

- Water tablets (diuretics) and medicines to treat high blood pressure
- Medicines for heart problems (e.g. digoxin)
- Thyroid hormones
- Medicines which may cause a dry mouth (e.g. tricyclic antidepressants), medicines to reduce your child's appetite or stimulant medicines
- Ergot alkaloids (for migraine)
- Oxytocin (to induce labour and stop excessive bleeding after the birth)

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicines you have bought for your child, including herbal and homeopathic remedies.

### How to give this medicine

Check the seal is not broken before first use. If it is, do not give the medicine.

Use the measuring spoon provided (the small end measures 2.5 ml and the big end measures 5 ml).

Age	How much to give	How often to give
Children of 6 to 12 years	Two 5 ml spoonfuls	3 or 4 times a day. <b>Don't give more than eight 5 ml spoonfuls in 24 hours.</b>

Give this medicine to your child to swallow.

Do not give to children under 6 years.

Do not give more than the amount recommended above.

Do not give this medicine for more than 5 days, unless your child's doctor tells you to.

If your child's symptoms worsen at any time, talk to a pharmacist or doctor.

If your child's cough comes back, stop giving this medicine and talk to a pharmacist or doctor.

If your child's symptoms do not go away, talk to your child's doctor.

**! If you give too much:** Talk to a doctor straight away.

### Possible side effects

Most people will not have problems, but some may get some.

**! If your child gets any of these serious side effects, stop giving the medicine. See a doctor at once:**

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)
- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with this medicine. See section 'Before you take this medicine'
- **Frequency not known: frequency cannot be estimated from the available data**
- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
- Stop using Boots Cough & Decongestant Syrup 6 Years Plus immediately and seek urgent medical attention if you develop symptoms that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:
  - severe headache with a sudden onset
  - feeling sick
  - vomiting
  - confusion
  - seizures changes in vision
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis)
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy).

**! If your child gets any of these side effects, stop giving the medicine:**

- Hallucinations
- Restlessness
- Sleep disturbances
- If your child gets any of the following side effects see your pharmacist or doctor:
  - Other allergic reactions such as skin rash
  - Feeling sick, being sick, stomach discomfort, dry mouth, thirst
  - Anxiety, feelings of paranoia, irritability, feeling excited, difficulty sleeping, headache
  - Tremors, muscle weakness, giddiness, sweating
  - Fast, slow or irregular heart beat, palpitations
  - High blood pressure
  - Difficulty in passing urine
  - Return of congestion, if you have given the medicine for a long time

**If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.**

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### How to store this medicine

Do not store above 25°C.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the bottle label or the end flap of the carton. After this date return any unused product to your nearest pharmacy for safe disposal.

### What is in this medicine

Each 5 ml of syrup contains Guaifenesin 50 mg, Pseudoephedrine Hydrochloride 10 mg, which are the active ingredients.

As well as the active ingredients, the syrup also contains purified water, maltitol liquid (E965), glycerol (E422), ethanol (4,8 vol %), citric acid, sodium citrate, acesulfame potassium, potassium sorbate (E202), hyetellose, flavours (blackcurrant, levomenthol, vanilla).

The pack contains 100 ml of clear, blackcurrant flavoured syrup.

### Who makes this medicine

Manufactured for the Marketing Authorisation Holder The Boots Company PLC Nottingham NG2 3AA by BCM Ltd Nottingham, NG2 3AA

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If you would like any further information about this medicine please contact The Boots Company PLC Nottingham NG2 3AA

### Treating coughs and colds in children

It's normal for children to get 8 or more colds in a year, however gradually they build up immunity and get fewer colds. Most colds will get better within a few days and you may not need to do more than keep your child comfortable until they get over it.

Antibiotics will not help to treat a cold as they are caused by viruses and not bacteria.

Follow these simple steps, which may help your child overcome their cough or cold:

- 1. If your child is hot or has a fever:** Increase the amount of fluid your child normally drinks. Lower their temperature with a Paracetamol or Ibuprofen medicine, which is suitable for children. (Paracetamol is not suitable for children under 2 months. Ibuprofen is not suitable for children under 3 months).

Your pharmacist will be able to help you find a suitable product if in doubt.

**2. For coughs:** Although it may be distressing to hear your child cough, the coughing itself serves an important purpose. It helps to clear phlegm on the chest or mucus from the nose. Give your child plenty of lukewarm clear fluids to drink, which may help loosen the phlegm and relax the airways.

**3. To help with breathing:** Plain saline nose drops, available from your pharmacy, can help babies with blocked noses who are having trouble feeding.

### Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information: Product name: Boots Cough and Decongestant Syrup 6 Years Plus

Reference number: 00014/0545

This is a service provided by the Royal National Institute of Blind People.