

Information for the user



Dry Cough & Congestion Relief Oral Solution

Dextromethorphan Hydrobromide 10 mg/5 ml, Pseudoephedrine Hydrochloride 30 mg/5 ml

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 take 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

What this medicine is for

This medicine contains Dextromethorphan, a cough suppressant, which acts to reduce coughing. It also contains Pseudoephedrine, a decongestant, which acts to relieve a blocked nose.

It can be used to relieve symptoms of dry and tickly coughs, blocked sinuses and catarrh. Dry coughs do not produce phlegm or mucus on the chest.

For children, 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 take this medicine

This medicine can be taken by adults and children of 6 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

✕ Do not take:

- **If you are allergic** to any of the ingredients in this medicine (see “What is in this medicine”)
- **If you are allergic to other decongestants**
- **If you have severe kidney problems**
- **If you have heart or blood vessel disease**
- **If you have high blood pressure** (including that due to a tumour near your kidney)
- **If you have diabetes**
- **If you have an overactive thyroid**
- **If you have raised pressure in the eye** (glaucoma)
- **If you have difficulty breathing**
- **If you have a long-term cough** or one which produces lots of phlegm
- **If you are having an asthma attack**
- **If you have difficulty in passing urine**
- **If you are taking any of these medicines:**
 - Monoamine oxidase inhibitors or moclobemide (for depression), or have taken them in the last 14 days

- Medicines which may cause a dry mouth (e.g. tricyclic antidepressants)
- Medicines to reduce your appetite or stimulant medicines
- Selective serotonin reuptake inhibitors (for depression)
- Medicines called beta-blockers (normally for heart problems)
- Other decongestants or medicines containing Pseudoephedrine
- Other cough and cold medicines
- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains sucrose)
- **If you are a man with prostate problems**
- **If you are pregnant or breastfeeding**

! Talk to your pharmacist or doctor:

- If you have other kidney problems (see "Do not take")
- If you have liver problems or angina
- If you are treating a child who is prone to allergies
- If you are taking any other medicines or are under the care of a doctor (see "If you take other medicines")
- If you intend to treat a child of 6 to 11 years
- If you are on a low salt (sodium) diet (each 5 ml spoonful contains 14.78 mg of sodium, which may be harmful to you)
- If you are dependent on alcohol or have epilepsy (this medicine contains alcohol, which may be harmful to you)

If you develop a feverish generalised erythema associated with pustules, stop taking 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 you develop these gastro-intestinal symptoms, stop taking this medicine and contact your doctor or seek medical attention immediately. See 'Possible side effects' section.

Other important information

If you are going into hospital for an operation tell the doctor that you are taking this medicine.

Driving and using machines: This medicine may make you feel dizzy or drowsy. Do not drive or use machines until you are sure you are not affected.

Do not drink alcohol (e.g. wine, beer, spirits) whilst taking this medicine. Alcohol increases the risk of side effects occurring and may make you feel more drowsy.

Information for people with diabetes: Each 5 ml spoonful contains 2.65 g of sucrose.

Information about some of the ingredients in this medicine: Each 5 ml spoonful contains 77.76 mg alcohol (ethanol) equivalent to 2 ml of beer or 0.8 ml of wine.

If you take other medicines

! This medicine contains Pseudoephedrine. Do not take with any other products that contain this ingredient.

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

- Medicines to treat high blood pressure
- Medicines for heart problems (e.g. digoxin)
- Ergot alkaloids (for migraine)
- Oxytocin (to induce labour and stop excessive bleeding after the birth)
- Medicines for allergies
- Sedatives or other medicines that make you feel sleepy
- Medicines for mental health conditions

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

✓ How to take this medicine

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

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

Age	How much to take	How often to take
Adults and children of 12 years and over	Two 5 ml spoonfuls	3 times a day
Children of 6 to 11 years	One 5 ml spoonful	3 times a day

This medicine should be swallowed. (For oral use).

Do not give to children under 6 years.

Do not take more than the amount recommended above.

Do not give this medicine to a child for more than 5 days, unless their doctor tells you to.

If you are treating a child and their symptoms worsen at any time, talk to a pharmacist or doctor.

If symptoms do not go away talk to your doctor.

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

Possible side effects

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

! If you get any of these serious side effects, stop taking this 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. Stop using Dry Cough and Congestion Relief Oral Solution if you develop these symptoms and contact your doctor or seek medical attention immediately. See section 'Before you take this medicine'.

Frequency not known:

Inflammation of the colon due to insufficient blood supply (ischaemic colitis)

! If you get any of these side effects, stop taking this medicine:

- Hallucinations
- Restlessness
- Sleep disturbances

If you get any of the following side effects see your pharmacist or doctor:

- Other allergic reactions such as skin rash
- Feeling sick, being sick, diarrhoea
- Feeling drowsy, dizzy, excited, confused or nervous
- Headache, anxiety, feelings of paranoia, irritability, fits, tremors, difficulty sleeping
- Fast, slow or irregular heart beat, palpitations and very rarely chest pain
- High blood pressure
- A very high temperature
- Breathing problems
- Difficulty in passing urine
- Very rarely bowel problems

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

How to store this medicine

This medicine does not require any special storage conditions. 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 end flap of the carton or on the label edge. After this date return any unused product to your nearest pharmacy for safe disposal.

What is in this medicine

Each 5 ml of oral solution contains Dextromethorphan Hydrobromide 10 mg, Pseudoephedrine Hydrochloride 30 mg, which are the active ingredients.

As well as the active ingredients, the solution also contains liquid sugar (containing sucrose), glycerol (E422), purified water, ethanol 96% (alcohol), sodium citrate, citric acid monohydrate, hydroxyethylcellulose, sodium saccharin, domiphen bromide, quinoline yellow (E104), flavours (peardrop, peach, levomenthol).

The pack contains 120 ml of clear yellow syrupy liquid.

Who makes this medicine

Manufactured by BCM Ltd Nottingham NG2 3AA UK for the MAH: The Boots Company PLC
Nottingham NG2 3AA, UK
Leaflet prepared June 2019

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

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 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:

1890 708091 (ROI only)

and ask for Boots Medical Information

Please be ready to give the following information:

Product Name: Boots Pharmaceuticals Dry Cough & Congestion Relief Oral Solution

Reference Number: 4/53/1