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Boots Decongestant with Pain Relief Tablets (Paracetamol, Pseudoephedrine Hydrochloride)

Information for the user

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 Paracetamol, an analgesic, which acts to relieve pain and reduce fever. It also contains Pseudoephedrine, a decongestant, which acts to relieve a blocked nose. It can be used to relieve the symptoms of colds and flu, including aches and pains, headache, blocked nose and sinuses and to reduce fever.

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 acute (sudden) or chronic (long-term) kidney disease or kidney failure
- If you have heart or blood vessel disease, including poor circulation in your hands or feet
- If you have severe liver problems
- If you have high blood pressure or hypertension not controlled by your medication (including that due to a tumour near your kidney)
- If you have diabetes
- If you have an overactive thyroid
- If you have glaucoma or you have been told you have raised pressure in the eye
- If you are taking any of these medicines:
 - Monoamine oxidase inhibitors or moclobemide (for depression), or have taken them within the last 14 days
 - Medicines called beta-blockers (normally for heart problems)
 - Other decongestants
- If you are pregnant or breastfeeding

Talk to your pharmacist or doctor:

- If you have other kidney or liver problems (including a disease caused by drinking alcohol)
- If you are dependent on alcohol
- If you are a man with prostate problems

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.

- Reduction of blood flow to your optic nerve may occur with pseudoephedrine. If you develop sudden loss of vision, stop taking Boots Decongestant with Pain Relief Tablets 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 this medicine immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see 'Possible side effects' for symptoms).

One of the active ingredients in this medicine, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more of this medicine than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see 'Possible side effects' section).

Other important information

Do not drink alcohol (e.g. wine, beer, spirits) whilst taking this medicine.

Information about some of the ingredients in this medicine

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

If you take other medicines

This medicine contains paracetamol.

Do not take with any other paracetamol-containing products.

Before you take these tablets, 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)
- Medicines which may cause a dry mouth (e.g. tricyclic antidepressants)
- Medicines to reduce your appetite or stimulant medicines
- Ergot alkaloids (for migraine)
- Oxytocin (to induce labour and stop excessive bleeding after the birth)
- Medicines for epilepsy
- Contraceptive tablets
- Non-steroidal anti-inflammatory drugs (for pain and swelling)
- Warfarin or other blood thinners – if you take warfarin you can take occasional amounts of this medicine, but talk to your doctor first before you take it on a regular basis
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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 foil is not broken before use. If it is, do not take that tablet.

Age	How many	How often
Adults and children of 12 years and over	One tablet	3 or 4 times in 24 hours, if you need to. Don't take more than 4 tablets in any 24 hours.

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Children of 6 to 11 years	Half a tablet	4 times in 24 hours, if you need to. Don't take more than 4 half tablets in any 24 hours.
Don't take more often than every four hours.		

Swallow the tablet with water.

Do not give to children under 6 years.

Do not take more than the amount recommended above.

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

Do not take this medicine for more than 5 days, unless your doctor tells you to.

If symptoms do not go away talk to your doctor.

- **If you take too many tablets:** Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

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 the tablets. See a doctor at once:**

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)
- Very rare cases of serious skin reactions have been reported. This may include peeling, blistering and lesions of the skin
- 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:

Inflammation of the colon due to insufficient blood supply (ischaemic colitis).
Reduced blood flow to the optic nerve, loss of vision (Ischaemic optic neuropathy)

Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Stop using this medicine 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

If you get any of these side effects, stop taking the tablets:

- Hallucinations
- Restlessness
- Sleep disturbances

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

- Other allergic reactions including skin rash
- Feeling sick, being sick
- Anxiety, feelings of paranoia, irritability, feeling excited, tremors, headache, difficulty sleeping
- Fast, slow or irregular heart beat, palpitations
- High blood pressure
- Difficulty in passing urine
- Unusual bruising or infections such as sore throats – this may be a sign of very rare changes in the blood

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 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 30°C.

Store in the original package.

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 foil or on 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 tablet contains Paracetamol 500 mg, Pseudoephedrine Hydrochloride 60 mg, which are the active ingredients.

As well as the active ingredients, the tablets also contain microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate, quinoline yellow (E104).

The pack contains 12 yellow capsule shaped tablets.

Who makes this medicine

Manufactured for the Marketing Authorisation holder The Boots Company PLC Nottingham
NG2 3AA by Famar AVE Anthoussa Attiki
15349 Greece

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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 Decongestant with Pain Relief Tablets

Reference number: 00014/0594

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

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