SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots Decongestant with Pain Relief Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	*mg/tab*
Paracetamol	500.0
Pseudoephedrine hydrochloride	60.0

3 PHARMACEUTICAL FORM

Tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of the symptoms of colds and influenza including feverishness, aches and pains, headache, nasal and sinus congestion (blocked nose and sinuses).
For oral administration.

4.2 Posology and method of administration

Adults and children over 12 years
One tablet to be taken three or four times a day, up to a maximum daily dose of 4 tablets (240mg pseudoephedrine and 2g paracetamol).

Elderly
Although no specific studies have been carried out in this age group, there is no need for dosage reduction in the elderly.

Children 6 to 12 years
Half a tablet to be taken four times a day, up to a maximum daily dose of 2 tablets

(120mg pseudoephedrine and 1g paracetamol).

This medicine is contraindicated in children under 6 years of age (see section 4.3).

Children of 6-12 years of age: not to be used for more than 5 days without the advice of a doctor. Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

Administration in those with hepatic disorders
Care should be taken in administering this product to patients with severe hepatic impairment.

Administration in those with renal disorders
Care should be taken in administering this product to patients with moderate to severe renal impairment.

Warning: Do not exceed the stated dose.

Keep all medicines out of the sight and reach of children.

4.3 Contraindications

Hypersensitivity to the active substances or any of the excipients.
Severe renal impairment
Cardiovascular disease including hypertension, severe hypertension or uncontrolled hypertension and peripheral vascular disease.
Severe acute or chronic kidney disease/ renal failure
Diabetes mellitus
Phaeochromocytoma
Hyperthyroidism
Closed angle glaucoma or where intraocular pressure is raised
Severe liver disease
Concomitant use of other sympathomimetic decongestants
Monoamine oxidase inhibitors (MAOIs, or within 14 days of stopping treatment, see section 4.5)
Beta-blockers – (see section 4.5)
Not to be used in children under the age of 6 years

4.4 Special warnings and precautions for use

Caution in moderate to severe renal impairment.
Should be taken with caution by patients with hepatic impairment, prostatic enlargement and those with alcohol dependence.
If any of the following occur, the product should be stopped:
Hallucinations
Restlessness
Sleep disturbances

Severe Skin reactions
Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with

fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of this medicine should be discontinued and appropriate measures taken if needed.

Ischaemic colitis
Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Ischaemic optic neuropathy
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3). Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as the underlying cause of HAGMA in patients with multiple risk factors.

Glutathione deficiency can also increase the risk of hepatotoxicity with paracetamol use, even at therapeutic doses. Caution is advised for patients at risk of glutathione depletion (See section 4.9).

Hepatotoxicity at therapeutic dose
Cases of paracetamol induced hepatotoxicity, including fatal cases, have been reported in patients taking paracetamol at doses within the therapeutic range. These cases were reported in patients with one or more

risk factors for hepatotoxicity including low body weight (adults <50 kg), renal and hepatic impairment, chronic alcoholism, concomitant intake of hepatotoxic drugs and in acute and chronic malnutrition (low reserves of hepatic glutathione). Paracetamol should be administered with caution to patients with these risk factors. Caution is also advised in patients on concomitant treatment with drugs that induce hepatic enzymes and in conditions which may predispose to glutathione deficiency (see section 4.9).

Dosage adjustment of paracetamol should be considered where there are risk factors for glutathione deficiency or hepatotoxicity and for those of low weight (for adults those weighing less than 50kg).

Risks of abuse
Pseudoephedrine carries the risk of abuse. Increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 4.2).

Not to be given to children under 6 years.
Do not give this medicine to children aged 6-12 for more than five days, unless your doctor agrees.
If symptoms persist, consult your doctor.
Do not take with any other decongestant-containing products.
Do not take with any other paracetamol-containing products.

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

Label
Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Leaflet or combination label/leaflet
Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4.5 Interaction with other medicinal products and other forms of interaction

Pseudoephedrine

MAOIs and/or RIMAs: should not be given to patients treated with MAOIs or within 14 days of stopping treatment: increased risk of hypertensive crisis.

Moclobemide: risk of hypertensive crisis.

Antihypertensives (including adrenergic neurone blockers & beta-blockers): this product may block the hypotensive effects.

Cardiac glycosides: increased risk of dysrhythmias.

Ergot alkaloids (ergotamine & methysergide): increased risk of ergotism.

Appetite suppressants and amphetamine-like psychostimulants: risk of hypertension.

Oxytocin – risk of hypertension.

Enhances effects of **anticholinergic drugs** (such as TCAs).

Concomitant use of this medicine with tricyclic antidepressants and sympathomimetic agents such as decongestants may cause a rise in blood pressure.

Paracetamol

Alcohol and drugs which induce hepatic microsomal enzymes, such as anticonvulsants and oral contraceptive steroids, may increase the hepatotoxicity of paracetamol, particularly after overdose.

Chronic use of paracetamol enhances the effects of anticoagulants.

Concurrent use of paracetamol with NSAIDs may increase the risk of adverse renal effects. The prolonged combined use of these compounds may increase the risk of renal damage.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risk factors (see section 4.4).

4.6 Fertility, pregnancy, and lactation

Boots Decongestant with Pain Relief Tablets should not be used during pregnancy or breastfeeding unless the potential benefit outweighs the risk to the foetus or breastfed infant.

Pregnancy

Paracetamol

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency

Pseudoephedrine

There are limited amount of data on the use of pseudoephedrine in pregnant women. The use of pseudoephedrine during the first trimester of pregnancy has been associated with an increased frequency of gastroschisis (a developmental defect in the abdominal wall with intestinal herniation) and of small intestinal atresia (congenital obstruction of small intestine). Due to the vasoconstrictive

properties of pseudoephedrine, it may induce a reduction in uteroplacental circulation.
Pseudoephedrine is not recommended in pregnancy

Breastfeeding
Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding. Pseudoephedrine has been detected in human milk with a small percentage of the maternal dose potentially administered to the breastfed infant. Irritability and disturbed sleep have been reported in breastfed infants. Pseudoephedrine may suppress lactation.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Pseudoephedrine

Immune system disorders:
Hypersensitivity reactions, including cross-sensitivity that may occur with other sympathomimetics.

Cardiac disorders:
Tachycardia, palpitations, other cardiac dysrhythmias.

Vascular disorders:
Hypertension.

Gastrointestinal disorders:
Nausea and/or vomiting.
Frequency unknown: Ischaemic colitis

Nervous system disorders:
Headache, Tremor

Frequency unknown: Posterior reversible encephalopathy syndrome (PRES) (see section 4.4), Reversible cerebral vasoconstriction syndrome (RCVS) (see section 4.4)

Renal and urinary disorders:

Psychiatric disorders:
Anxiety, restlessness, irritability, excitability, hallucinations (particularly in children), insomnia, sleep disturbance, paranoid delusions

Skin and subcutaneous tissue disorders:
Skin reactions including rash. Frequency unknown - Severe skin reactions, including acute generalized exanthematous pustulosis (AGEP).

Eye disorders: Frequency unknown: Ischaemic optic neuropathy

Paracetamol
Hypersensitivity to paracetamol, including a skin rash, may occur.

Very rare cases of serious skin reactions have been reported.

Blood and lymphatic system disorders:
There have rarely been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

Metabolism and nutrition disorders:
Frequency "Not known" (cannot be estimated from the available data): High anion gap metabolic acidosis. Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Paracetamol
Liver damage is possible in patients who have taken more than recommended doses of paracetamol.
Ingestion of paracetamol at therapeutic doses may lead to liver damage if the patient has risk factors (see below).

Risk Factors
If the patient

a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes

OR

b) Regularly consumes ethanol in excess of recommended amounts

OR

c) Is likely to be glutathione deplete e.g. diet (malnutrition, fasting, dietary restrictions, eating disorders, and starvation), catabolic states (sepsis), cachexia, and chronic illness (cystic fibrosis, liver disease, HIV, and muscular dystrophy).

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral odema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of the overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section. Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable) but results should not delay initiation of treatment beyond 8 hours after ingestion, as the effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside of hospital.

Pseudoephedrine

Symptoms

Symptoms of overdosage include irritability, restlessness, palpitations, hypertension, difficulty in micturition, nausea, vomiting, thirst and convulsions. In severe overdosage gastric lavage and aspiration should be performed. Symptomatic and supportive measures should be undertaken, particularly with regard to cardiovascular and respiratory systems. Convulsions should be controlled with intravenous diazepam. Chlorpromazine may be used to control marked excitement and hallucinations. Severe hypertension may need to be treated with an alpha-adrenoreceptor blocking drug, such as phentolamine. A beta blocker may be required to control cardiac arrhythmias.

Management

Symptomatic and supportive measures should be undertaken, particularly with regard to the cardiovascular and respiratory systems. Convulsions should be controlled with intravenous diazepam. Chlorpromazine may be used to control marked excitement and hallucinations. Severe hypertension

may need to be treated with an alpha-adrenoreceptor blocking drug, such as phentolamine. A beta blocker may be required to control cardiac arrhythmias.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol is a peripherally acting analgesic with antipyretic activity. Pseudoephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has alpha and beta adrenergic activity and some stimulant effect on the central nervous system. The sympathomimetic effect of pseudoephedrine produces vasoconstriction which in turn relieves nasal congestion.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 hours. Plasma protein binding is negligible at usual therapeutic concentrations, although this is dose-dependent.

The rate and extent of paracetamol absorption is normal in the elderly but plasma half life is longer and paracetamol clearance lower than in young adults.

In renal impairment though the mean plasma half-life of paracetamol is similar in normal and renally impaired subjects at 2-8 hours, from 8-24 hours paracetamol is eliminated less rapidly. An increase in the interval between doses of paracetamol has been recommended for adults with chronic renal failure.

With severe hepatic impairment the mean plasma half life of paracetamol is significantly prolonged (by approximately 75%). The clinical significance of this is however unclear, as no evidence exists of drug accumulation or hepatotoxicity in patients with liver disease.

Pseudoephedrine is readily and completely absorbed from the gastrointestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted in the urine unchanged. It has an elimination half-life of 5 to 8 hours but its urinary elimination and hence half-life is pH dependent. Pseudoephedrine is rapidly distributed throughout the body, its volume of distribution being 2 to 3L/Kg bodyweight.

5.3 Preclinical safety data

Pseudoephedrine

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC

Paracetamol

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised maize starch
Microcrystalline cellulose
Sodium lauryl sulphate
Magnesium stearate
Quinoline yellow (E104)
Croscarmellose sodium.

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30 ^{o}C.
Store in the original package.

6.5 Nature and contents of container

A child-resistant push through pack of opaque 250 micron PVC/40gsm PVdC blisters, heat sealed to 35gsm Glassine paper/9 micron soft temper aluminium foil.
Pack sizes: 6, 12.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC or The Boots Company PLC - Trading as BCM
1 Thane Road West
Nottingham
NG2 3AA

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0594

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/03/2009

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07/10/2025