SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Decongestant Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient
Pseudoephedrine hydrochloride 60mg/tablet

3. PHARMACEUTICAL FORM

Tablets

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the relief of nasal and sinus congestion without causing drowsiness.

For oral administration.

4.2. Posology and Method of Administration

Adults and children over 12 years: One tablet if necessary, up to four times daily at intervals of not less than 4 hours.

Children under 12 years: Not recommended.

Elderly: There is no need for dosage reduction in the elderly.

4.3 Contraindications

Hypersensitivity to any of the ingredients. Avoid in patients with cardiovascular disease, hypertension, or uncontrolled hypertension, severe acute or chronic kidney disease/renal failure, diabetes mellitus, closed angle glaucoma, hyperthyroidism, and phaeochromocytoma.

Concomitant use of sympathomimetic decongestants, beta-blockers or monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping MAOI treatment (see section 4.5).

4.4 Special warnings and precautions for use

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 Decongestant Tablets 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.

Caution is advised in patients with prostatic enlargement.

If any of the following occur, this medicine should be stopped:

- Hallucinations
- Restlessness
- Sleep disturbances

If symptoms are not controlled by Boots Decongestant Tablets, medical advice should be sought.

Keep all medicines out of the reach of children.

Warning: Do not exceed the stated dose.

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

4.5 Interaction with other medicinal products and other forms of interaction

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

Beta-blockers: this medicine may block the hypotensive effects

Cardiac glycosides: (such as digoxin) increased risk of dysrhythmias

Anticholinergic drugs: (such as tricyclic antidepressants) enhanced effects

Appetite suppressants and amphetamine-like psychostimulants: risk of hypertension

Oxytocin – risk of hypertension

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

4.6 Fertility, pregnancy and lactation

Pregnancy

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.

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

Adverse effects may include dry mouth, anxiety, restlessness, tremor, insomnia, tachycardia, cardiac arrhythmias, palpitations, hypertension, nausea, vomiting,

headache and occasionally urinary retention in males and skin rashes. Hallucinations have been reported rarely, particularly in children.

Immune system disorders

Hypersensitivity reactions, including cross sensitivity that may occur with other sympathomimetics.

Skin and subcutaneous tissue disorders:

Frequency unknown: Severe skin reactions, including acute generalized exanthematous pustulosis (AGEP).

Gastrointestinal Disorders:

Nausea, vomiting, dry mouth

Frequency unknown: Ischaemic colitis

Eye disorders:

Frequency unknown: Ischaemic optic neuropathy

Nervous system disorders:

Headache, dizziness, tremor

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

Cardiac disorders:

Tachycardia, palpitations, cardiac arrhythmias

Renal and urinary disorders:

Urinary retention in males.

Vascular disorders:

Hypertension

Psychiatric disorders:

Sleep disturbance, insomnia, restlessness, anxiety, hallucinations (particularly in children).

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

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.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

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

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. Pre-clinical Safety Data

There are no preclinical data of relevance to the prescriber which are additional to that
already included.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Sodium Starch Glycolate
Maize Starch prd
Microcrystalline Cellulose
Pregelled Maize Starch
Purified Water
Stearic Acid

6.2. Incompatibilities

None are known.

6.3. Shelf-Life

36 months.

6.4. Special Precautions for Storage

None.

6.5 Nature and contents of container

Blister pack of white or clear 250 microns PVC coated with 40gsm PVdC and 20 micron aluminium foil.

Pack sizes: 6, 7, 10, 12 tablets.

6.6. Instructions for Use, Handling and Disposal

None.

7. MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham
NG2 3AA

8. MARKETING AUTHORISATION NUMBER(S)

PL 00014/0375

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

28 January 1988 / 17 December 1997

10 DATE OF REVISION OF THE TEXT

10/02/2025