SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Boots Blocked Nose Relief 12mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	*mg/cap*
Phenylephrine Hydrochloride	12.00

3 PHARMACEUTICAL FORM

Capsule, hard (capsule)

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of nasal congestion associated with colds and hayfever.

4.2 Posology and method of administration

Adults and children over 12 years: One capsule if necessary, up to four times daily.

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, high blood pressure, diabetes mellitus, closed angle glaucoma, hyperthyroidism, prostatic enlargement and phaeochromocytoma. Patients being

treated with monamine oxidase inhibitors or within 14 days of ceasing such treatment (see section 4.5).

4.4 Special warnings and precautions for use

This medicine should be used with caution in patients with occlusive vascular disease including Raynaud's Phenomenon.

Do not take for longer than 7 days, unless your doctor agrees.

If symptoms do not go away talk to your doctor.

Keep all medicines out of the reach of children.

Warning: Do not exceed the stated dose.

Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency of glucose-galactose malabsorbtion should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Should not be given to patients being treated with monoamine oxidase inhibitors or within 14 days of stopping such treatment. May enhance the effects of anticholinergic drugs such as tricyclic antidepressants. May increase the possibility of arrhythmias in digitalised patients. May enhance the cardiovascular effects of other sympathomimetic amines (e.g. decongestants).

This medicine should not be taken together with vasodilators, Beta-blockers or enzyme inducers such as alcohol.

4.6 Pregnancy and lactation

The safety of this medicine during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to phenylephrine, the use of the product during pregnancy should be avoided. In addition, because phenylephrine may reduce placental perfusion, the product should not be used in patients with a history of pre-eclampsia. In view of the lack of data on the use of phenylephrine during lactation, this medicine should not be used during breast feeding.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Adverse effects may include tachycardia, cardiac arrhythmias, palpitations, hypertension, nausea, vomiting, headache and occasionally urinary retention in males.

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.

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

Phenylephrine is a sympathomimetic agent with mainly direct effects on adrenergic receptors. It has predominantly alpha adrenergic activity and is without stimulating effects on the central nervous system. The sympathomimetic effect of phenylephrine produces vasoconstriction which in turn relieves nasal congestion.

5.2 Pharmacokinetic properties

Phenylephrine is readily absorbed after oral administration but is subject to extensive presystemic metabolism, much of which occurs in the enterocytes. As a consequence, systemic bioavailability is only about 40%. Following oral administration, peak plasma concentrations are achieved in 1-2 hours. The mean plasma half life is in the range 2-3 hours. Penetration into the brain appears to be minimal.

Following absorption, the drug is extensively metabolised in the liver. Both phenylephrine and its metabolites are excreted in the urine.

The volume of distribution is between 200 and 500 litres, but there are no data on the extent of plasma protein binding.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised maize starch

Dried maize starch

Lactose monohydrate

Magnesium stearate

Hard Gelatin Capsule (Gelatin, Quinoline Yellow E104, Titanium dioxide E171)

Ink (Black Iron Oxide E172, Shellac, Propylene glycol)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Blister pack of pigmented 250 micron PVC coated with 40gsm PVDC and 20 micron aluminium foil.

Pack sizes: 5, 6, 7, 10, 12, 14, 18, 20, 21, 24, 25, 28, 30, 36, 48, 50.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC

1 Thane Road West

Nottingham

NG2 3AA

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0593

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/09/2005

10 DATE OF REVISION OF THE TEXT

23 March 2015