SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Syrup for Decongestion 30mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	%w/v
Pseudoephedrine Hydrochloride	0.6

3 PHARMACEUTICAL FORM

Syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

For oral administration.

Adults and children over 12 years: Two 5ml spoonfuls four times a day.

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, diabetes mellitus, closed angle glaucoma, hyperthyroidism, prostatic enlargement and phaeochromocytoma.

4.4 Special warnings and precautions for use

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.

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.

4.6 Pregnancy and lactation

The safety of Decongestant Syrup during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to pseudoephedrine, the use of the product during pregnancy should be avoided. The amounts of pseudoephedrine secreted into breast milk are considered to be too small to be harmful.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

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

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 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

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 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltitol solution
Hydroxyethylcellulose
Glycerin
Alcohol 96%
Sodium saccharin (76% Cryst)
Domiphen bromide
Levomenthol
Raspberry flavour 1740 3970 IFF (contains Propylene glycol)
Citric acid
Sodium citrate
Purified water

6.2 Incompatibilities
None known.

6.3 Shelf life
24 months.

6.4 Special precautions for storage
Do not store above 30°C.

6.5 Nature and Contents of Container

Clear glass bottle with child resistant closure fitted with expanded polythene liner.

Pack size: 100ml

6.6 Special precautions for disposal
Not applicable.

7 MARKETING AUTHORISATION HOLDER
ASPAR PHARMACEUTICALS LIMITED

29-30 CAPITOL WAY

COLINDALE

LONDON

NW9 OEQ

UNITED KINGDOM

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