Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Meltus Decongestant

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pseudoephedrine hydrochloride 30 mg/5ml.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral Liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a nasal decongestant.

For the short term symptomatic relief of conditions such as the common cold and influenza, allergic and vasomotor rhinitis (relief of such symptoms as blocked sinuses, stuffed up noses).

4.2 Posology and method of adminstration

Route of administration: oral

To be taken three times a day

Adults and children over 12 years: two 5ml spoonfuls.
Children 6-12 years: one 5ml spoonful.
Children 2-5 years: one 2.5ml spoonful.
Under 2 years: not recommended.

4.3 Contraindications

Contraindicated in patients who have previously shown intolerance to pseudoephedrine. It is contraindicated in persons under treatment with MAOIs, and within 2 weeks of cessation of treatment. It is also contraindicated in patients with severe hypertension or severe coronary artery disease.

4.4 Special warnings and precautions for use

Although pseudoephedrine has virtually no pressor effects in patients with normal blood pressure, Meltus Decongestant should be used with caution in patients taking antihypertensive agents, tricyclic anti-depressants, or other sympathomimetic agents such as decongestants, appetite suppressants and amphetamine like psycho-stimulants. The effects of a single dose on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment. As with other sympathomimetic agents, caution should be exercised in patients with uncontrolled diabetes, hyperthyroidism, elevated intraocular pressure and prostatic enlargement.

Label Warnings: WARNING: Do not exceed the stated dose

As with all medicines, if you are pregnant or currently taking other medicine, consult your doctor or pharmacist before taking this product. If symptoms persist consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

The effect of antihypertensive agents which modify sympathetic activity may be partially reversed by Meltus Decongestant. Concomitant use of Meltus Decongestant with other sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants, and amphetamine-like psychostimulants or with MAOIs which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.

The antibacterial agent furazolidine is known to cause a dose related inhibition of Monoamine Oxidase Inhibitors and although there are no reports of hypertensive crises having occurred, it should not be administered at the same time as Meltus Decongestant.

4.6 Pregnancy and lactation

Although pseudoephedrine has been in widespread use for many years without apparent ill consequences, there is no specific data on its use in pregnancy. Caution should therefore be exercised by balancing the potential benefit of treatment against any possible hazards.

Systemic administration of pseudoephedrine up to 50 times the human dose in rats and up to 35 times the human dose in rabbits, did not produce teratogenic effects. It has been estimated that approximately 0.5 to 0.7% of a single dose of pseudoephedrine ingested by a mother will be excreted in the breast milk over 24 hours.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

Side effects may include symptoms of central nervous system excitation such as restlessness. In some patients pseudoephedrine may cause tachycardia and insomnia, sleep disturbances and hallucinations have been reported.

A fixed drug eruption to pseudoephedrine, taking the form of erythematous nummular patches has been reported but is a rare occurrence. Urinary retention has been reported in male patients in whom prostatic enlargement could have been an important predisposing factor.

4.9 Overdose

Symptoms include irritability, restlessness, tremor, convulsions, palpitations, hypertension and difficulty in micturition.

Emergency procedures: Gastric lavage and supportive measures for respiration and circulation should be performed if indicated. Convulsions should be controlled with an anticonvulsant. Catheterisation of the bladder may be necessary. If desired the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally effective upper respiratory tract decongestant.

5.2 Pharmacokinetic properties

Pseudoephedrine is readily and completely absorbed from the gastrointestinal tract following oral administration, with no presystemic metabolism. It achieves peak plasma concentration between 1 and 3 hours after oral dosing. It is eliminated largely unchanged in the urine (55-90%) in 24 hours, although there is some metabolism in the liver (<1%) by N-demethylation. It has a plasma half-life of 5-8 hours following oral dosing, but its urinary elimination, and hence its half-life, is pH dependant such that elimination will be increased in subjects with acidic urine and decreased in subjects with alkaline urine.

Pseudoephedrine is rapidly distributed throughout the body. Its volume of distribution is 2-3 L/Kg body weight but there are no reports of the extent of plasma binding and similarly, although CNS effects are observed, there is no specific information concerning its penetration into the CNS.

It is excreted in breast milk at concentrations consistently higher than those in maternal plasma. The fraction of dose excreted in milk has been estimated at approximately 0.5% of a single oral dose over 24 hours. Pseudoephedrine is likely to cross the placenta. The elimination of pseudoephedrine is reduced in renal impairment and with deteriorating renal function in the elderly.

Oral absorption:	>95%
Presystemic metabolism:	Negligible
Plasma half-life:	5.4 - 8 hours
Volume of distribution:	2-3 L/Kg
Plasma protein binding:	-

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol syrup (non crystallising)
Menthol
Loganberry flavour 500195E
Methylhydroxybenzoate
Propylhydroxybenzoate
Ethanol (96%)
Glycerol
Sodium saccharin
Sodium cyclamate
Carmellose sodium
Water

6.2 Incompatibilities

None stated.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light. Do not refrigerate.

6.5 Nature and contents of container

Amber glass sirop bottle with tamper evident polypropylene copolymer cap with unfaced closed cell expanded polyethylene wad, in an individual carton containing 100, 140 or 200 ml of product and a 5 ml spoon with a 2.5 ml graduation.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 258/47/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7 November 1996

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10 DATE OF REVISION OF THE TEXT

March 2003